CANCER PATIENT DECISION-MAKING AND RELATIONAL AUTONOMY RELATED TO CLINICAL TRIAL PARTICIPATION

by

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Abstract

Clinical trials (CTs) in cancer care play an essential role in advancing knowledge and improving patient care. Low CT enrolment, however, threatens this field of science and may prevent people with cancer from benefiting from the latest therapeutic interventions. The aim of this research was to explore cancer patients’ CT decision-making process and how they exercise relational autonomy within this process. Relational autonomy acknowledges patients are situated within a larger relational and socio-political context that is characterized by inherent power differentials and social inequities that may influence CT decisions.

The objectives of this research were to: a) understand cancer patients’ decision-making process related to CT participation and how they exercise relational autonomy within this process; b) examine the personal, social, and system influences on cancer patients’ decision-making process related to CT participation and their ability to exercise their relational autonomy; and c) identify the best practices utilized by CT personnel that support cancer patients in exercising their relational autonomy in the CT decision-making process. Two different yet complementary methodologies, interpretive description and grounded theory, guided in-depth interviews with 12 CT personnel, 40 breast and prostate cancer patients, and 11 support persons to address the objectives.

Three major themes were uncovered that impact cancer patients’ decision-making process and ability to exercise their relational autonomy: (1) power differentials between patients and physicians, (2) therapeutic misconception, and (3) inequities in access to CTs. The overarching construct ‘no wo/man is an island’ captured patients’ CT decision-making process and experiences of autonomy, including the relational complexity of CT decisions and the key influences on this process. Results from this research highlight how CT
decision-making is a complex endeavor comprised of key phases and processes that are not only personally but also socially and structurally located. Practice implications of this research include targeted education for CT personnel and patients to equalize power relationships within CT recruitment. In addition, standardization of cancer drug approval, better monitoring and follow-up cancer care, and a more accessible and quality healthcare system can address structural barriers in order to support patients’ relational autonomy within the context of CTs.
Preface

This dissertation is based on a national collaboration that received funding from the Canadian Institutes of Health Research (CIHR) open operating grant competition (2011-2013). I initially conceived the research project design with significant support from Dr. Lynda Balneaves. Dr. Balneaves is listed as the principal investigator of the project since CIHR policies prevent students from being listed as the principal investigator. Dr. Anita Ho, co-applicant, was involved in the data analysis, drawing on her expertise in trust and autonomy in medical decision making. Dr. Kim Chi, Medical Director of the BC Cancer Agency (BCCA) Clinical Trials Department, and Dr. Karen Gelmon, Scientist at the BCCA, were co-applicants. They assisted with recruitment of the interview participants and offered clinical insights into the final theory. Dr. Harriet Richardson, collaborator, is a Project Coordinator with the NCIC Clinical Trials Group (CTG) and an Assistant Professor at Queen’s University. She is an important liaison with the NCIC CTG, which will facilitate future dissemination activities based on this research. Two graduate research assistants, Ms. Genevieve Breau and Ms. Maryam Matean, assisted in the recruitment of participants, data collection, and data coding.

I initially conceived the study design with the support of Dr. Balneaves. I took a leadership role in collecting the data, performing the analysis of the data, interpreting the findings from data analysis, and writing the dissertation chapters. Dr. Balneaves was instrumental in advising on the writing of the research document. She was the initial reviewer for the drafts of each chapter of this dissertation and provided significant guidance and feedback regarding the data interpretation and analysis. My doctoral committee members, Drs. Anita Ho and Patricia Rodney, provided ongoing guidance and input throughout the
research process. They also provided significant feedback on each of the chapters included in this dissertation. Sarah Brumwell provided editorial service in accordance with the Editors’ Association of Canada *Guidelines for Ethical Editing of Theses/Dissertations*.

I composed Chapter Two, the systematic literature review, with significant edits and feedback from Dr. Balneaves in order to prepare the document for submission to the CIHR operating grant competition. A version of this chapter has been submitted to a peer-reviewed journal. Dr. Lynda Balneaves was instrumental in shaping this chapter for journal submission and is included as a co-author on the submitted manuscript.

I composed Chapter Three, methodology, with significant edits and feedback from Dr. Balneaves in order to prepare the document for submission to the CIHR operating grant competition. Grant members, Dr. Kim Chi and Dr. Karen Gelmon provided guidance regarding participant recruitment methods.

Approval from the University of British Columbia (UBC) Behavioural Research Ethics Board was obtained for the research chapters, Chapters Four and Five, involving interviews with human subjects (certificate number: H10-02904).
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I would also like to thank my doctoral committee members, Drs. Paddy Rodney and Anita Ho. Both reviewed several iterations of each chapter and provided helpful comments and feedback. I am grateful for the enthusiasm they exhibited towards the project and for their insights that improved my work.

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Dedication

To my family
Introduction

The overarching problem that this dissertation addresses is the lack of knowledge concerning how patients with cancer experience the clinical trial (CT) decision-making process, with particular attention paid to the personal, social and structural influences on this process. In this introduction, I provide a brief overview of essential background information for this research, outline the research objectives, and introduce the overall structure of the dissertation.

Background: The Canadian Healthcare System

Canada’s healthcare system is provincially funded and delivered with support from the federal government in terms of cash and tax transfer payments. In order to receive federal payment for healthcare costs, provinces and territories must demonstrate that their health plans are aligned with the principles of the Canada Health Act (1985). The principles include *public administration, comprehensiveness, universality, portability, and accessibility*. Public administration requires that health plans be delivered on a not-for-profit basis. Comprehensiveness means all residents are covered for “medically necessary” health services. Universality requires public insurance plans to cover all residents according to the same terms and conditions. Portability allows residents to be treated by their public health plans wherever they are across Canada. Finally, accessibility requires access to insured services without direct or indirect financial charge or discrimination based on age, health status, or ability to pay (Council of Canadians 2010). These conditions are meant to ensure universal access to quality healthcare for all Canadians regardless of financial or other barriers. It also allows the federal government to have some control over the provincial administration of healthcare (Council of Canadians 2010).
In 2002, Commissioner Roy Romanow published a monumental report on the future of public healthcare in Canada (Commission on the Future of Health Care in Canada & Romanow 2002). In the report, Romanow identified serious, countrywide disparities in access to care that challenge the values of the Canada Health Act and the long-term sustainability of the system. He also identified a fragmented prescription drug system, which has resulted in disparities of coverage across the country. Even though Pharmacare (provincial insurance programs for prescription drugs) was not considered an insured healthcare service under the original provision of the Canada Health Act, Romanow argued that drugs are increasingly required for the successful management or treatment of illness and should be integrated within the healthcare system. Now, over a decade later, disparities based on income, education, sex and geography continue to challenge the Canadian healthcare system (Asada, Yoshida & Whipp 2013), including how care is provided to those living with cancer (Penner et al. 2012).

**Cancer Incidence**

As disparities in health care are increasing in Canada, so too is the incidence of cancer. According to the Canadian Cancer Society, cancer is the leading cause of death in Canada. In total, 29% of men and 24% of women will die from this disease, with the incidence of new cancer diagnoses expected to increase across the country due to the growing and aging population. It is expected that 45% of men and 40% of women will develop cancer during their lifetimes, with breast and prostate cancer predicted to be the most common new diagnoses (Canadian Cancer Society 2012).

Cancer care delivery, like other healthcare services, is a provincial responsibility, with most provinces delivering services through regional operations (Sullivan et al. 2004).
Timely access to cancer treatment and prevention is necessary for improved health outcomes and quality of life and to control the high incidence of the disease (Berrino et al. 2007). However, there is variation in incidence rates of cancer across Canada and within provinces due to differences in the populations, risk factors, and early detection behaviour/activities (Canadian Cancer Society 2012). Death rates also vary between regions, arguably because of inequitable access to cancer screening and treatment (Canadian Cancer Society 2012). In a recent comprehensive review of the Canadian literature, Maddison and colleagues identified inequities in access to cancer screening, radiotherapy, and end-of-life care services based on income, age, and geographic location (Maddison et al. 2011). For example, cancer patients with lower income and those who live far from a cancer centre are less likely to access treatment services, such as systemic therapy (Bairati, Jobin, Fillion, Larochelle & Vincent 2007; Maddison et al. 2011; Saint-Jacques et al. 2008).

Access to cancer drugs is vitally important for medical care as new therapeutic biotechnologies and pharmacogenetics offer unprecedented control of disease, yet Pharmacare is not yet covered by the insured services provision of the Canada Health Act. Instead, each province is responsible for evaluating and deciding which drugs will be covered under their own insurance plans, resulting in discrepancies between provinces regarding the drugs that are currently approved and available to cancer patients (Standing Senate Committee on Social Affairs 2012). As a consequence, inequities exist in relation to access to cancer drugs across Canada. A recent workshop report (Richter 2010) identified the following as barriers to cancer drug access; however, it is important to note that these barriers may also exist for drugs for many other chronic conditions:

- Out of pocket cost for patients who do not have insurance for drugs administered out
of hospital;

- Private insurance policies that no longer guarantee coverage;

- Variations in coverage among provincial plans – different provinces cover different treatments;

- Timely coverage of new drugs by provincial and territorial plans.

**Cancer Clinical Trials**

CTs are used to evaluate new cancer interventions and provide the foundation of evidence-based practice. Randomized controlled trials (RCTs) are generally recognized as the “gold standard” because they are designed to minimize the risk of study bias and provide objective evidence about an intervention. When the results of many RCTs are pooled, they can produce the best available evidence about an intervention or drugs at the population level (Rogers 2004).

Increasingly, CTs are becoming part of the cancer care system as a way for patients to obtain the latest and expensive drug therapies. Although not all CTs involve drugs, they are often the primary focus of this type of research.¹ CTs are conducted in phases that begin after basic biomedical research on a drug has been completed in a laboratory on cell and mice models. The following table outlines the various phases of clinical research.

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¹ CTs are an “investigation in respect of a drug for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological, or pharmacodynamic effects of the drug, identify
Table 1.1 – Clinical Trial Phases

<table>
<thead>
<tr>
<th>Trial Phase</th>
<th>Description</th>
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<tr>
<td>Phase 0</td>
<td>Trials that administer a very small dose of a chemical or biologic agent or other types of interventions to a small number of people to gather preliminary information about how the agent is processed by and affects the body.</td>
</tr>
<tr>
<td>Phase I</td>
<td>Trials that test an intervention for safety in a small group of participants.</td>
</tr>
<tr>
<td>Phase II</td>
<td>Trials that administer an intervention to a larger group of participants to test its effectiveness. These trials also continue to look at the safety of interventions.</td>
</tr>
<tr>
<td>Phase III</td>
<td>Trials that compare the effectiveness of a new intervention, or new use of an existing intervention, with the current standard of care. These trials also examine how the side effects of the new intervention compare with those of the usual treatment. These trials usually involve large groups of people who are randomized to one of two trial arms.</td>
</tr>
<tr>
<td>Phase IV</td>
<td>Trials that are conducted after a drug has been approved by a governing body (e.g., Health Canada) in order to evaluate its effectiveness and long-term safety.</td>
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CTs may compare an experimental intervention against a placebo. They may include randomization, where participants are assigned to arms of the study by chance, which often occurs in Phase III trials. They might also be single- or double-blind controlled studies where either the participant or the participant and the research team are blinded to which medication is being administered. These procedures are used to reduce bias in the study findings.

There are two ways cancer CTs are typically sponsored in Canada. Trials are either implemented by cooperative groups or by the pharmaceutical industry. Cooperative groups

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2 This table has been adapted from the National Cancer Institute’s website. Retrieved December 30 2013, from http://www.cancer.gov/cancertopics/factsheet/clinicaltrials/clinical-trials.
include the National Cancer Institute of Canada (NCIC) clinical trials group (CTG), a national oncology group primarily made up of academic investigators and physicians, which receives core funding from the Canadian Cancer Society Research Institute and is supported by the Canadian Cancer Society. Both cooperative and pharmaceutical sponsors are responsible for ensuring local administrative costs of trials, illustrating the complexity of the CT system in Canada. These include costs related to trial operations, such as human resources for audit, monitoring, and safety reporting, and operational and technological infrastructure, such as meeting administration, sample sharing, databases and biobanking. Costs also include payment to institutions to support CT recruitment of human subjects and related laboratory testing that are increasingly required in studies (The Standing Senate Committee on Social Affairs 2012). Between 1980 and 2012, the NCIC CTG carried out 255 Phase III trials involving more than 65,000 participants and 188 Phase I or II studies involving more than 5,000 participants (Canadian Cancer Society 2012).

Cancer CTs may be conducted in physician offices, cancer centres, academic healthcare organizations, clinics and community hospitals. Patients typically gain access to cancer CTs through their physicians. However, current accrual to cancer trials is extremely low. The national average for adult patient recruitment to Canadian cancer CTs in 2009 was 7% with the provinces ranging from 2% to 11% (Canadian Cancer Research Alliance 2011). Increasingly, cancer CTs are occurring internationally due to the pressures of patient accrual. In a recent analysis of trial accrual performance among adult oncology studies in the United States (US), Cheng et al (2011) reported a total of 81.5% of trials did not achieve accrual goals within the anticipated accrual period. This resulted in trials remaining open longer, thus resulting in additional costs, or closing earlier without achieving the minimum projected
accrual as defined within the study protocol. Low accrual compromises the success of CTs, wastes valuable resources, and squanders an opportunity for improving patient outcomes. As such, future research must explore opportunities for increasing patient accrual to CTs, while continuing to ensure human research subjects’ safety and wellbeing throughout the research process.

**Critique and Need for Current Research**

Since the Nuremberg trials in 1947, the protection of human research subjects has been an international moral imperative (Rothman 2003). Several codes and guidelines have been developed world-wide to support the ethical conduct of clinical research (World Medical Association 1964, 1975, 1983, 1989, 1996, 2000, 2002, 2004, 2008), including the Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd edition (TCPS 2) (Canadian Institutes of Health Research 2010) and the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979). Three basic ethical principles are addressed within these research ethics guidelines: respect for persons, beneficence and justice. While these principles are all relevant to the conduct of CTs, the principle of respect for persons and its application through the informed consent process is particularly relevant to CT recruitment and accrual.

Informed consent procedures entail providing autonomous individuals the right to choose to participate or not in research based on their own considered judgment (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979). Autonomy typically refers to individuals’ ability to freely determine and act upon their values and/or preferences. The influence of others is often seen as detrimental to autonomy because it can prevent individuals from making their own choices. Previous
research on cancer patients’ CT decision-making has been dominated by an individualist approach to autonomy. The focus has been on individual patients’ decisions with significant attention to the kinds of information required by patients to ensure their informed consent to trial participation (see Albrecht, Penner & Ruckdeschel 2003; Albrecht, Ruckdeschel, Riddle, Blanchard, Penner, Coovers & Quinn 2003; Loh, Butow, Brown & Boyle 2002). For example, Brown, Butow, Boyle and Tattersall (2004) found that within the informed consent process, oncologists scored poorly on communicating essential information to patients, such as explaining randomization and alternative therapy options available if the patient were to decline the trial. Also, many oncologists were found to implicitly urge patients to consider either standard care or trial participation, thus potentially comprising the voluntariness of patients’ informed consent (Brown et al. 2004).

However, the field of healthcare ethics is increasingly adopting the broader notion of “relational autonomy”, which recognizes the importance of social circumstances and significant relationships on individuals’ self-determination and informed consent (Beauchamp & Childress 2012; Sherwin 1998). This relational aspect is reflected in some studies that have broadened the examination of physician-patient communication to include the influence of family members on communication and patients’ informed consent. For example, Albrecht, Penner & Ruckdeschel (2008) developed a holistic model of communication by examining the complex dynamics between physicians, patients and significant others, and the bearing these relationships had on patients’ CT decisions.

Relational autonomy (as will be described more fully in Chapter One) acknowledges the inescapable interplay of social and structural forces on individuals’ decision-making processes (Sherwin 1998). Respecting persons’ relational autonomy in the context of human
subjects’ research thus requires attending not only to the personal aspects of cancer patients’ CT decision-making process but also the broader social and structural dimensions that impact their autonomy within this process (Sherwin 1998). This requires attending to not only familial or significant relationships influential to cancer patients’ autonomy but also to the broader socio-political environment in which these relationships are developed and sustained. Thus, the theoretical lens of relational autonomy relates well to understanding and addressing larger equity challenges of health care delivery and the structural complexity of CTs on individual cancer patients’ decision making.

**Research Objectives**

The purpose of this dissertation is to explore cancer patients’ decision-making process about CT participation through the lens of relational autonomy in order to develop new insights and practice and research recommendations about cancer patients’ CT decision-making and trial recruitment procedures. Accordingly, the objectives of this study are to:

- *Understand* cancer patients’ decision-making process related to CT participation and how they exercise relational autonomy within this process;

- *Examine* the personal, social, and structural influences on cancer patients’ decision-making process related to CT participation and their ability to exercise their relational autonomy;

- *Identify* the best practices utilized by CT personnel that support cancer patients in exercising their relational autonomy in the CT decision-making process.

The overall outcome of this dissertation research is an in-depth description and theory of the nature of CT decision-making through the lens of relational autonomy. This theory will
provide a foundation for the development of decision support strategies that will enhance how Canadians living with cancer are approached, recruited, and enrolled in cancer CTs.

**Structure of the Dissertation**

This dissertation is comprised of six chapters, plus this Introduction. *Chapter One* introduces relational autonomy as the guiding theoretical framework that informs multiple aspects of the dissertation research, including the primary study design, data collection and analysis. The purpose of Chapter One is to provide an overview of relational autonomy theory, which is contrasted with more traditional accounts of autonomy. Differing feminist theories of relational autonomy are discussed and Susan Sherwin’s account is argued as most applicable to this dissertation research.

*Chapter Two* provides a literature review in order to situate the current study within the relevant field of research. An overview of studies examining cancer patient treatment decision making as well as CT decision making is presented, since there is often overlap as trials are discussed in the treatment context. Key gaps in the literature are identified with regards to the socio-political influences on cancer patients’ decision-making processes that are important for patients’ relational autonomy. This sets the stage for the empirical chapters that follow.

*Chapter Three* presents the methodology of the dissertation research. This dissertation uses two different but complementary qualitative methodologies: interpretive description and grounded theory. Breast and prostate cancer patients, and their support persons, were interviewed for the grounded theory study. CT personnel were interviewed for the interpretive descriptive study. Grounded theory and critical feminist analysis combined data from both studies in order to obtain perspectives relevant to personal, social, and
structural influences on patients’ CT decision-making processes. An overview of the study designs, participant recruitment, interview conduct, and data analysis is provided in this chapter.

Chapters Four and Five of this dissertation are based on data collected through open-ended interviews with cancer patients, support persons, and CT personnel in 2011 and 2012. Chapter Four uses interpretive description to explore CT personnel perspectives (e.g., oncologists, CT nurses) about cancer patients’ experience of autonomy within the CT decision-making process and best practices for supporting cancer patients’ autonomy. Chapter Five explores breast and prostate cancer patients’ decision-making process related to CT participation in order to develop a theory “grounded” in their actual experiences.

Finally, Chapter Six uses relational autonomy theory and a critical feminist analysis to further explore and analyze the socio-political findings from Chapters Four and Five. Key themes that are discussed include issues of justice and equitable access to CTs, therapeutic misconception and the dual role of the oncologist-investigator, and social influences. Issues relating to gender that may place undue pressure on patients’ relational autonomy in the context of breast and prostate cancer patients’ CT decision-making processes are explored. Practice recommendations are proposed to support cancer patients’ relational autonomy within their CT decision-making processes. Finally, the limitations of the current research are considered and future research is proposed to advance the field.
Chapter One: Relational Autonomy as Theoretical Lens

In this dissertation, the theoretical lens of relational autonomy was used to explore the ethical dimensions of clinical trial (CT) decision making from the cancer patient’s perspective. The purpose of this chapter is to outline an autonomy theory in light of feminist notions of relational autonomy. First, the concept of autonomy for healthcare and trial decision making is examined and placed in philosophical context. This is then followed by feminist critiques and an elaboration on the unique features of a “socially-situated” (Sherwin 1998) or relational conception of autonomy. It is argued that Sherwin’s relational autonomy theory is most applicable to this dissertation. Practical ways in which the theory and associated critical feminist lens guided the dissertation are outlined.

Traditional Accounts of Autonomy

Western bioethics presumes the importance of autonomy as a right for individuals to determine for themselves what shall be done to their bodies (Mappes & DeGrazia 2006). In the research context, patients exercise this right by choosing whether to participate in CTs based on their own considered judgment and providing informed consent to participate (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979). Autonomy to provide informed consent requires patients exhibit: a) intentionality to perform the relevant action; b) understanding of the relevant information; c) freedom from internal constraints (e.g., depression, addiction); and d) freedom from external constraints (e.g., physical barriers, coercion) (Mappes & DeGrazia 2006). Autonomous patients are thus presumed to demonstrate capability to understand and appreciate the decision at hand and be free from coercion or external influence so that their respective
values and choices are not unduly influenced or biased by healthcare providers or others (Tomlinson 1986).

The writings of two prominent philosophers, in particular, have heavily influenced the predominant interpretation of autonomy within the healthcare context: Immanuel Kant (1724-1804) and John Stuart Mill (1806-1873).\(^3\) According to Kant, persons are those beings who are intellectually capable of deriving for themselves and acting in accordance with the rational law. Autonomy, according to some interpretations of Kant, involves self-sufficiency and the freedom of will from external considerations that allow an individual to act on the basis of rational reasons alone.\(^4\) Rational reasons are those that appeal to only universal maxims to guide action instead of reasons based on self-interest or natural inclinations. Autonomous persons are therefore rational people who are expected to only act from reason (emotional aspects of decisions are non-reasoned). They should be afforded due respect and, as such, must not be treated as mere means to an end, but as ends themselves: “so act as to treat humanity, whether in your own person or in that of any other, never as a means, but always at the same time as an end” (Kant 1964, p.96).

Whereas Kant’s writings may have influenced how rationality evolved as an important criterion for autonomy, the philosophical writings of John Stuart Mill (1806-1873) may have imparted the second influence on the concept of autonomy, namely the notion of

\(^3\) Mill’s writings could be said to offer more of a political view of the boundaries of personal decision-making, whereas the moral value of autonomy is often derived from the philosophy of Immanuel Kant (1724-1804). See Thomas May (2005) for a discussion of the distinction between moral and political requirements of autonomy. Moral autonomy requires adherence to rational law. Political autonomy requires respect for decisions within the political sphere.

\(^4\) However, whether Kant’s writings provide moral justification of autonomy as self-sufficiency and independence is debated in the literature. See Secker (1999).
individual independence. According to Mill, autonomy, or more accurately, liberty, refers to persons’ ability to determine for themselves what constitutes the good life. The emphasis, however, is on “negative liberty” or freedom from the interference of others in order for the individual to actively shape one’s own goals, pursue one’s own projects, and flourish in the personal development of one’s own capacities and character (Mill 1974). Above all, the individual is seen as best positioned to direct oneself in the manner one sees fit, provided that he or she does not cause harm or infringe on others’ expressions of freedom to do the same.

**Feminist Theories of Autonomy**

Feminists reject the view that the influence of others always impedes self-determination and that independent and rational decision-making are ideal characteristics of the autonomous person (Barclay 2000). Instead, feminists support a *relational* concept of the self and corresponding theory of autonomy.\(^5\)

Although feminist accounts vary, relational autonomy theorists recognize the inherent intersubjectivity of persons and that important relationships, as well as social, historical, and political institutions, significantly influence self-determination. Complete freedom from interference in self-determination is seen as unrealistic and even undesirable as it negates, for

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\(^5\) Increasingly, mainstream ethicists also support a more relational concept of autonomy. The thinking of Beachamp and Childress (2012), authors of a prominent bioethics text now in its seventh edition, has evolved from recognizing autonomy as an individualistic concept in their first edition of the textbook to acknowledging its relational attributes in later editions. Despite the evolution of the concept of autonomy within the field of bioethics, health care providers still misinterpret respect for autonomy to require non-interference with patients’ rational decision making (Ells, Hunt & Chambers-Evans 2011).
example, the importance of social relationships in fostering persons’ development of autonomy capacities. Furthermore, the socio-political environment influences patients’ ‘rational’ choices such that those patients with more social and economic resources are more likely to be deemed rational, and thus, autonomous to make decisions (Secker 1999b).

Ascriptions of rationality may be contingent upon the social and economic circumstances of the decision maker. For example, the rationality and reasonableness of a preference for discharge home may be contingent upon the ability to pay for homecare services. Two otherwise identically situated patients, one who can pay for home care and one who cannot, may be judged quite differently by healthcare providers. When the patient who can pay for these services states a preference for discharge, her decision may be deemed reasonable. By contrast, when a patient who cannot pay for these services states this preference, her decision may be deemed unreasonable. Inequitable distributions of goods and resources are expressed in assymetrical ascriptions of rationality; patients who are disadvantaged are more likely to be judged irrational on these grounds alone. This is clearly problematic. An attractive feature of relational accounts of autonomy is that these accounts attune us to the ways in which social, political, economic and other contextual factors influence both patients’ exercise of autonomy and healthcare providers’ assessment of patients’ autonomy.

In general, to be relationally autonomous, persons must at least possess adequate capacities for reflecting upon, identifying, re-affirming, or revising their identity-conferring values, goals and commitments (e.g., Meyers 1989; Sherwin 1998). Autonomy is a continuous process of developing and refining these capacities through experiences and opportunities for self-determination. This account is so far consistent with traditional theories
except that feminists recognize social influences and the socio-political context as central to the development and realization of self-determination. The broader socio-political context inevitably influences personal decision making, including persons’ sense of what is important, their guiding values, goals, and commitments, relationships with others, and senses of identity (Mackenzie & Stoljar 2000; Nedelsky 1989; Sherwin 1998). Socio-political contexts and relationships can facilitate autonomy by providing access to quality education, healthcare, and financial resources that allow persons to develop or exercise their autonomous capacities. Socioeconomic disparities (e.g., lack of education, income, social resources), asymmetries of power, status and knowledge, disparities in healthcare access, and the undue or coercive influence of family and friends, however, can impede persons’ autonomy. Mackenzie and Stoljar (2000) identify three distinct but inter-related levels in which socio-political context can influence autonomy. These include:

- At the level of belief and desire formation;
- In the development of capacities and competencies necessary for autonomy;
- In limiting a person’s ability to act on autonomous desires or make autonomous choices (p. 21).

In order to redress oppression and unjust socioeconomic conditions that disempower some groups in exercising their autonomy, relational autonomy theories include a strong commitment to social justice. Social justice refers to the degree to which society supports the conditions necessary for all persons to exercise capacities, express experiences, and participate in determining actions while simultaneously respecting group differences without oppression (Young 1990). In healthcare, social justice may require improving the social and
material conditions for disadvantaged groups that influence their health status and ability to exercise capacities.

Feminists employ a critical stance in order to identify instances of power differences and social inequities that may further undermine social justice and relational autonomy so that they may be addressed. Critical feminism recognizes that persons are embedded in and emerge from social relations that are organized by power dimensions rooted in inequalities experienced by racial, cultural, ethnic, class, and gender groups (Qin 2004). In particular, critical feminism allows the impact of gender socialization and its intersection with other inequalities on relational autonomy to be made visible and addressed. The following section details the relationship between relational autonomy and gender.

**Relational Autonomy and Gender**

Sherwin and other feminist theorists argue that the traditional theoretical account of autonomy is inherently masculine because it upholds rationality, independence, and self-reliance, as ideal characteristics of the autonomous person (Mackenzie & Stoljar 2000; Sherwin 1998). The result is to deny the autonomy of those who do not meet the ideal, especially persons who are dependent on others because of illness (Sherwin 1998).

Gender and its interactions with other variables have important implications for autonomy from a relational standpoint. For example, Sherwin and other feminists (Dodds 2000; Secker 1999b), argue that the rationality of women and other oppressed groups is more likely to be questioned, and they are viewed as lacking autonomy because of sexism, ageism, and other stereotypes. Further, women are more likely to be viewed as embodying feminine characteristics, such as emotion and dependency, which are in direct opposition to traditional conceptions of autonomy. When gender intersects with class, women who have fewer
socioeconomic resources may be less likely to develop capacities for autonomy and more likely to be perceived as lacking competence (see, for example, Secker 1999a).

In comparison, men who otherwise would be viewed as meeting the autonomy ideal might, as cancer patients, fall short of this ideal. As Arthur Frank contends, illnesses such as cancer can destabilize previous ways of knowing the self; it is “a loss of the ‘destination and map’ that had previously guided the ill person’s life” (Frank 1997, p.1). A relational autonomy lens acknowledges gender and associated variables as important contextual features that may constrain or promote patients’ development and enactment of personal autonomy when making treatment or trial decisions.6

**Spectrum of Relational Autonomy Theories**

Relational theorists differ on which capacities are necessary for autonomy and whether meeting capacity conditions is sufficient to ensure an autonomous self. Broadly speaking, theories of relational autonomy can be located on a spectrum, with procedural accounts on one end and substantive accounts on the other end (Mackenzie & Stoljar 2000).7

**Procedural Relational Autonomy**

At one end of the spectrum are *procedural* notions of relational autonomy. These accounts specify that a person need only exercise a range of capacities for autonomy to be enacted without regard for the resulting desires, values, and commitments. Importantly, capacities are recognized as themselves developed or undermined in socio-political contexts.

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6 Several authors have explored the influence of masculinity and femininity on cancer patients’ self-identities. For a rich discussion, see Bush 2000; Gray, Fitch, Phillips, Labrecque and Fergus 2000; Oliffe 2005; Oliffe 2006.

7 According to Mackenzie and Stoljar, procedural conditions are necessary, although insufficient, for substantive accounts of relational autonomy (see 2000, p. 19).
Therefore, procedural accounts are also interested in the historical formation of capacities and whether the socio-political environment helped or hindered their development. For example, cancer patients who are from a paternalistic society might not have had opportunities to develop capacities for autonomy. Thus, their societal context has undermined their autonomy potential for making cancer treatment or trial decisions.

Diana Meyers’ theory of autonomy competency is a highly influential procedural account of relational autonomy (Meyers 1989). She argues that autonomy is an activity that consists of persons exercising a range of skills for self-direction, such as introspective or reflective skills, communication skills, reasoning skills, and imagination skills. By exercising these skills people come to grasp “who they are, what matters to them, how they want to develop or change, what constraints limit them and how they can best give expression to their integral desires, beliefs, affections, and values” (Meyers 1992, p. 126). Autonomous persons possess degrees of proficiency or competency in exercising these skills and may be more or less competent in some areas of self-determination than in others.

The socio-political environment is central to persons developing autonomy skills. In Meyers’s view, differential access to opportunities to practice autonomy skills may impede or promote autonomy. For example, larger social and cultural ideologies that exist in some societies that construct negative messages about women who are strong and self-interested may undermine some women’s ability to critically evaluate their own needs and preferences (for example, see Bottorff et al. 1998). Thus, a patient’s autonomy skills are limited by a socio-political landscape that creates subtle and powerful pressures on her self-determination. To the extent that the patient is limited by dominant and oppressive social conventions, she may require further opportunities to develop a more robust capacity for
self-reflection, which in turn requires social and cultural frameworks that support rather than undermine autonomy-promoting capacities.

**Substantive Relational Autonomy**

At the other end of the spectrum are *substantive* notions of relational autonomy. These perspectives consider not only a person’s capacity to enact autonomy (as in procedural theories) but also specify what sorts of desires, values, and commitments a person may legitimately hold.

Paul Benson (1994) argues that autonomous persons must have the ability to tell the difference between right and wrong or between rational and false beliefs. Whether a desire is legitimate or not depends upon the kinds of socialization a person has been subject to and whether it results in a person not being able to distinguish true and false norms underlying their action. Persons may fail “normative competence” when, for example, masculine norms of competition and risk-taking encourage men with cancer to participate in clinical trials (CTs) because they want to be seen as ‘macho’ and receiving the leading edge of treatment. The men’s sense of self-worth is equated with risk-taking as a result of their effective masculine socialization. As such, substantive theorists would identify these men as lacking some autonomy to the extent they have allowed a false norm to govern their lives.

Returning to the earlier discussion of the influence of social and cultural ideology on autonomy, even if a female patient with breast cancer was able to self-reflect and identify her own beliefs and values (thus satisfying the procedural account of autonomy), the patient’s ultimate conclusion that her needs are not important is problematic, according to substantive accounts, because it stems from the internalization of problematic social norms concerning women’s moral worth. Benson and other substantive theorists argue that a
person who holds personal desires that reflect oppressive socialization can never be fully autonomous, even if his/her reflective and critical capacities are intact (Benson 1994). This view seems to imply that others can override the person’s autonomy in the areas of their lives where the norm governs, and instead make decisions for them that are in their own best interests.

**Hybrid Account of Relational Autonomy**

In this dissertation I will rely upon Sherwin’s theory of relational autonomy (Sherwin 1998), which appears to be a hybrid of procedural and substantive notions of relational autonomy theories. As such, Sherwin’s theory possesses the strengths of both theories while avoiding many of their respective weaknesses. For example, a major weakness of substantive accounts is that they can exacerbate rather than ameliorate oppression (Mackenzie & Stoljar 2000). Members of already marginalized groups are deemed non-autonomous because they fail to meet rational or true standards set by strong substantive theorists. By contrast, the major weakness of procedural accounts is that they may not identify autonomy-undermining beliefs, thereby leaving persons vulnerable to internalized oppressive socialization. However, Sherwin (following Meyers’ theory) recognizes degrees of relational autonomy, whereby autonomy fluctuates and exists on a continuum, thus avoiding the entrenchment of oppression associated with strong substantive accounts. Sherwin also suggests further conditions for autonomy that limit the potential for internalized oppression. She argues autonomous persons must exercise self-trust and self-worth. That is, persons must believe in their ability to determine who they are and what is important to them, and trust the judgements they make about themselves (McLeod & Sherwin 2000, p. 262). This limits the sorts of desires an autonomous person may hold, thus
guarding against internalized oppression, without going so far as to specify the actual content of an autonomous preference (as in strong substantive accounts).

Sherwin’s theory is categorized as weakly substantive because she argues that particular attitudes towards the self (e.g. self-worth and self-trust) are crucial for autonomy in addition to the capacity for critical reflection (McLeod & Sherwin 2000; Sherwin 1998). Similar to other feminist accounts, Sherwin argues that persons are, to a significant degree, socio-politically constructed. One’s attitudes towards oneself, like one’s capacities for engaging in activities that are constitutive of identity and autonomy, are fostered or hindered within interpersonal and political relationships of power and powerlessness (Sherwin 1998).

Relational autonomy applied to the context of CTs allows providers to appreciate how the broader socio-political environment may inform or frame the patient-oncologist relationship and influence, for example, which patients with cancer are offered a CT based on providers’ assumptions about their competence or economic status. Supporting cancer patients’ autonomy in this context requires addressing potential biases of providers, enabling patients to exercise their capacities and engaging in activities to promote social justice (Baylis, Kenny & Sherwin 2008; McLeod & Sherwin 2000; Sherwin 1998). This includes addressing unequal background conditions, such as differences in education, working conditions, and access to other healthcare resources (e.g., supportive cancer care) that limit the spectrum of meaningful choice options available and hinder patients’ development of autonomy capacities.

In this dissertation, I contend that relational autonomy is an ideal approach to understanding, exploring and, ultimately, supporting cancer patients’ decision-making process within the context of CT recruitment. As applied, the theory can guide the
development and maintenance of all persons’ autonomy skills over time, no matter the level of self-determination a person currently holds. All cancer patients, regardless of whether they appear independent or not, are inherently social beings whose healthcare decisions and capacities for autonomy are developed within and continually influenced by the socio-political context. Sherwin’s theory draws attention to how even those patients who appear autonomous from a traditional individualist perspective would have developed their autonomy skills with the assistance of a supportive socio-political context prior to the present healthcare encounter. At the same time, other individuals who appear to enact the traditional notion of autonomy may not have had a supportive social context, and thus, are not achieving the ideal of relational autonomy. These “fully autonomous” patients can still be supported through a relational autonomy lens in maintaining, rather than developing, their autonomy skills. For example, CT personnel play a key role in maintaining patients’ autonomy by engaging them in a shared decision-making process and providing them with meaningful information in an accessible format.

**Relational Autonomy as Guiding Theoretical Framework**

Sherwin’s theory is particularly suited to the present study for a number of reasons. First and foremost, she was the first feminist theorist known to apply relational autonomy specifically to the healthcare context (Sherwin 1998). Instead of focusing narrowly on informed consent as a way to respect patient autonomy (which is consistent with traditional autonomy theory), Sherwin uncovers how social context and power relationships inform and influences patients’ autonomy and healthcare decision-making processes more broadly. This requires uncovering the power differences that may exist between patients and healthcare
professionals due to differences in knowledge, status, and the fact that professionals play a gatekeeper role to health resources and CTs.

Furthermore, addressing oppression and unjust social conditions experienced by marginalized populations within healthcare and the broader community will promote greater relational autonomy within these groups. For example, paying attention to the larger healthcare context, Sherwin’s theory (like all other relational autonomy theories) draws attention to the kinds of options that are made available for patient choice or informed decision-making. She draws attention to the structural conditions underlying the options made available to patients and the potential for limiting patients’ relational autonomy by the absence of meaningful options because of, for example, differences in socioeconomic resources.

Patients’ relational autonomy may be greatly inhibited by certain opportunities not being placed on the table for consideration due to healthcare access issues and ability to pay. For example, cancer patients’ autonomy may be limited when they are unable to access a trial due to their geographical location or because their economic position prevents them from travelling to a study site. Thus, attention shifts away from the individual patient making healthcare choices to issues of social justice and access to basic goods and resources that support meaningful decision making.

Finally, Sherwin’s theory recognizes self-determination as an ongoing process that may be developed and refined. Even though a person may exhibit autonomy at one point in time, social and structural forces as well as personal experiences can cause person’s capacities to wax and wane in response to illness or new power dynamics. This especially corresponds with the proposed study’s emphasis on the process of cancer patient’s CT
decision making and the ongoing role that family, healthcare providers and policy-makers can play in enabling patient autonomy. Sherwin’s theory is thus appropriate as it allows exploration of how to best understand and subsequently support patients’ capacities for autonomy and attitudes towards the self within the provider-patient relationship. It also allows for broader social justice recommendations to apply to a wider circle of relationships, such as policy-makers, national institutes or advocacy groups, through policy and practice change.

Sherwin’s theory of relational autonomy (Sherwin 1998) was used to inform multiple aspects of the study, including the use of two methodologies to gain access to different social influences on patients’ CT decision-making process (i.e., interpretive description and grounded theory), and how and from whom the data was collected and subsequently analyzed. In keeping with relational autonomy theory, a critical feminist lens was applied to the analysis phases of the grounded theory research in order to explore gendered power differences in the context of CT decision-making process. Using a grounded theory analysis in conjunction with a critical feminist lens allows power dynamics within social processes to be made visible so that they can be addressed and potentially lead to the emancipation of vulnerable persons. A critical feminist lens was not applied to the analysis phase of the interpretive descriptive study because it was believed that the power hierarchy inherent in the patient-physician relationship and its influence on the CT decision-making process would be more visible from the perspective of patients rather than clinicians.

Grounded theory is informed by the fundamental tenets of symbolic interactionalism, which stipulate that humans are dynamic and always exist in relation to others. Social interaction mediates human action by causing one to interpret, revise or reconsider one’s
intention or purpose (Blumer 1969). Symbolic interactionalism has been criticized, however, for not theorizing power or for not situating instances of human action within a larger socio-political picture (Kushner 2003). Therefore, in this study, the addition of a critical feminist lens to the grounded theory analysis allowed exploration of the background conditions and power differences that exist for the study population, and more specifically, within patients’ CT decision-making process.

Important relationships also play a central role in relational autonomy theory. Therefore, the study population included not only breast and prostate cancer patients but also their support persons and CT personnel. CT personnel, in particular, were interviewed for the interpretive descriptive study to elaborate on larger, macro-level issues that would have bearing on patients’ CT decision-making processes and relational autonomy.

Triangulation of grounded theory, interpretive description and critical feminist analysis relates well to relational autonomy and its recognition of the socio-political context on persons’ self-determination.

By uncovering the socio-political dynamics (e.g., power relationships) and opportunities for enabling patients’ autonomy at the structural level, findings from this dissertation research will be able to inform the development of recruitment procedures and decision support interventions that will empower patients and create more autonomy-supportive CT practices.

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8 Triangulation refers to using two or more approaches to answer the research question, thus allowing for a comprehensive picture of the studied experience (Knafl & Breitmayer 1989). For further discussion about how triangulation relates to relational autonomy and the objectives of this dissertation see Chapter Two.
Chapter Two: Integrative Literature Review of Cancer Patient Decision Making About Clinical Trials with Implications for Patients' Relational Autonomy

The purpose of this chapter is to present an integrative review of the literature that summarizes the factors and contexts influencing cancer patient decision making related to treatment and clinical trial (CT) participation. The theoretical framework of relational autonomy is used to guide the organization of the research findings into personal, social, and structural influences. A secondary aim is to consider how socio-political influences impact patients’ relational autonomy in the context of CT decision-making. Both the treatment and CT decision-making literature is examined because CT discussions often arise as part of clinical care and are sometimes perceived by cancer patients and clinicians to offer an opportunity for state-of-the art or innovative therapy (American Society of Clinical Oncology 1997). Thus, literature describing cancer patients’ treatment decision-making processes may contribute to our understanding of patients’ CT decisions. This understanding is essential to the development of CT recruitment procedures that are better able to address the barriers to relational autonomy experienced by some cancer patients within their CT decision-making process. It also holds the potential to improve cancer patients’ overall cancer trajectory experience.

Methodology

I chose an integrative approach to guide my review of the literature for this dissertation. Whittemore and Knafl (2005) identify integrative reviews as most appropriate for collecting and synthesizing experimental and non-experimental research in order to add depth and breadth (e.g., rich and varied perspectives) to the phenomenon of interest. This approach is well suited to my dissertation where I am interested in ethical as well as
empirical inquiry, including both quantitative and qualitative research, to inform a comprehensive understanding of the current evidence of CT decision making in the context of cancer. Whittemore and Knafl’s (2005) integrative review process was selected due to its systematic approach to data collection, data extraction, and methods of analysis and synthesis, which enhanced the rigour of the review process and improved the accuracy of the conclusions. These strategies are described below.

**Methods**

The databases PubMed, CINAHL, and EMBASE were searched to locate relevant literature published between 1995 and 2012. Keywords entered into these searches included a combination of “cancer” or “neoplasm”, “decision-making”, “patient selection”, “patient participation”, and “clinical trial” or “randomized controlled trial.” Articles had to be written in English and limited to adult cancer populations. Studies were included in this review if they examined factors or contexts that may influence cancer patients’ decisions to participate in CTs. Research assessing intent or hypothetical decision-making was included, as were studies involving patients who had previously taken part in CTs and/or patients who had never been approached to participate in CTs. Systematic reviews examining CT participation in cancer populations were also identified. Research that examined decisions about participation in cancer screening trials, however, was excluded in order to narrow the scope of the review and because these patients may not be making decisions from the perspective of having a cancer diagnosis. To supplement results, a related literature search was conducted by replacing the initial keywords “clinical trial” or “randomized controlled trial” with the keyword “treatment.” Articles in the supplementary review also had to be written in English and limited to adult cancer populations. Only qualitative research focusing on cancer
patients’ decision-making process was included because the purpose was to shed further light on aspects of patients’ decision-making process that would be relevant to CT recruitment.

My doctoral research supervisor, Dr. Lynda Balneaves, and I independently examined titles and abstracts of articles to decide if each met the inclusion criteria and study aims. Disagreement was resolved through discussion and, where necessary, the full text article was accessed and assessed. Once consensus was obtained, I summarized all relevant articles in a literature review matrix to assist with critical evaluation of article findings and quality review of the studies. I developed a 2-point scale (high or low) to assess the quality of each article. A high score was provided to articles that demonstrated methodological or theoretical rigour and data relevance (Moher, Liberati, Tetzlaff, Altman, & PRISMA Group 2010). A low score was provided to articles that I determined did not meet these standards. None of the research in the matrix was subsequently excluded based on a low data quality assessment. Dr. Balneaves independently reviewed the matrix. Key categories of the matrix included author, title, country, study purpose, sample size and type, data collection method and design, outcome measures, key study findings, and study limitations.

**Results**

**Summary of Systematic Reviews**

Seven systematic reviews were identified in the initial literature search, 5 of which met PRISMA (Moher, Liberati, Tetzlaff, Altman, & PRISMA Group 2010) standards for reporting quality and were included in the present review (see Table 2.1.). One of these reviews included a meta-analysis of 33 original research articles addressing patient-identified barriers to participation in cancer CTs (Mills et al. 2006). The other systematic review included 9 primary research articles specifically addressing barriers to recruitment of older
patients into cancer CTs (Townsley, Selby, & Siu 2005). Another systematic review identified 33 articles that explored poor recruitment or non-participation in CTs within the field of cancer (Cox & McGarry 2003). Of the final two reviews, one evaluated 16 American studies that addressed factors influencing cancer patients’ CT decision-making (Biedrzycki 2010). The other review assessed barriers and facilitators to the participation of women and minorities in CTs in 22 studies (Schmotzer 2012).

**Limitations of systematic reviews.** Although these systematic reviews summarize the cancer CT participation literature, they face several limitations related to generalizability of the findings. Three of the systematic literature reviews were significantly limited in scope and unable to provide a comprehensive analysis of studies conducted to date. For example, one review was limited to addressing barriers to recruitment of older patients into cancer CTs (Townsley et al. 2005). Although this work is important, it cannot provide a broader understanding of the barriers to all adult cancer patients’ participation in CTs. Another of the reviews was limited to original research conducted in the United States and within a restricted timeframe (2004-2010) (Biedrzycki 2010). This significantly limits our understanding of the numerous personal-, social-, and structural-related factors associated with CT participation that are present across different ethno-cultural groups and cancer populations.

The systematic review and meta-analysis conducted by Mills et al. (2006) did provide a comprehensive overview of both quantitative and qualitative studies addressing patient-identified barriers to enrolment in CTs. Schmotzer’s review assessing barriers and facilitators to CT participation experienced by women and minorities is also relevant (Schmotzer 2012). The present literature review updates and expands this previous work by
highlighting the role of socio-political barriers to CT participation and the importance of interventions that support cancer patients’ relational autonomy in overcoming these barriers.

**Summary of Quantitative Literature**

In total, 36 quantitative studies were included in this review (see Table 2.2). None of these studies used experimental research methods. Twenty-four of the quantitative studies were descriptive surveys, three studies were retrospective chart reviews, two studies were case-control, six used multiple research methods, and one used a probability trade-off design. Of the quantitative studies, 20 were conducted in the United States, four in the United Kingdom, four in Canada, three in Australia, and one each in Italy, Korea, China, France and Taiwan. Two studies focused specifically on patient participation in Phase I CTs, three studies focused on Phase III trials, one study focused only on Phase II and III trials, one study focused on Phase I and II trials, and the remaining studies either focused on all forms of randomized trials or did not specify what type of CTs they focused on. All studies focused on cancer drug trials except for one study, which examined patient preferences related to a surgical cancer trial. Fifteen of the quantitative studies primarily assessed hypothetical participation or potential future willingness to participate in a CT. The remaining 21 studies reported on factors affecting accrual related to those patients who had been approached to participate in a CT, were currently enrolled in a CT, or had declined or withdrawn from a CT.

**Factors associated with CT participation: Findings from the quantitative literature.** Personal, social, and structural factors influencing CT participation were obtained from the literature. Personal factors were identified as demographic influences on cancer CT accrual such as patients’ age, ethnicity, gender, and disease stage. Personal factors also included patient characteristics that could affect accrual, such as patients’ values and beliefs
or knowledge and awareness of CTs. Social factors referred to relationships, such as cancer patients’ relationships with family or friends, or the patient-physician relationship, or demographics that had social components that could influence accrual. Structural factors related to institutional policies/procedures or the political environment within which CTs are conducted. This includes access to resources such as healthcare, insurance coverage, and institutions hosting cancer CTs. Findings were separated into these three broad categories because relational autonomy theory recognizes the influence of social context and structural factors on personal decision-making. Highlighting all three factors in a systematic fashion thus served to elucidate the relevance of these influences on cancer patients’ relational autonomy.

Although personal, social, and structural factors are presented as discrete concepts, I recognize there is fluidity between these categories and as such, overlap of influences can occur. For example, where patients live in relation to cancer centres hosting trials as well as their socioeconomic or financial resources to attend trials are interrelated and influence patients’ ability to participate in CTs. In fact, the intersectionality of these factors is itself socially and politically significant, since their configuration may marginalize certain populations in accessing CTs. This raises challenging justice considerations related to who gets the opportunity to participate in CTs and which populations benefit from research. Therefore, in the following sections some factors are discussed in one category and elaborated upon or corroborated in another. This is followed by a call for further consideration of the socio-political implications of these factors.

**Demographic factors influencing accrual.** Most of the quantitative body of research found that several demographic factors affect cancer patient accrual to CTs. For example,
several studies found that younger age was a predictor of CT participation (Advani et al. 2003; Ellis, Butow, Tattersall, Dunn, & Houssami 2001; Go, Frisby, & Lee 2006; Gross, Filardo, Mayne, & Krumholz 2005; Sateren et al. 2002) with the exception of one study, which found that older age was significantly associated with CT participation (Biedrzycki 2011). Race or ethnicity was also associated with greater participation in CTs, with Caucasian cancer patients participating in studies more frequently than other ethnic groups (Advani et al. 2003; Agrawal et al. 2006; Avis, Smith, Link, Hortobagyi, & Rivera 2006; Gross et al. 2005; Sateren et al. 2002).

Discrepancies between study findings were found to exist in relation to other personal demographics or characteristics. Some studies found more advanced disease stage (Kim et al. 2008; Klabunde, Springer, Butler, White, & Atkins 1999; Li & Jiang 2010) and fewer comorbidities (Kemeny et al. 2003) were associated with cancer patient participation in CTs. However, it seems reasonable to assume that patients with more advanced stage of disease would have more, not fewer, comorbidities. Contradictory findings were also apparent for the influence of gender on CT participation. One study found males have more favourable perceptions of CTs, which encourages their participation in cancer trials (Kim et al. 2008). Other studies found no statistically significant differences in cancer CT accrual based on gender (Klabunde et al. 1999; Sateren et al. 2002).

**Other personal factors that influence accrual.** Cancer patients’ beliefs and attitudes have been identified as being associated with CT participation. These include a strong desire to help others, perceived personal benefit, and hope for a cure (Agrawal et al. 2006; Avis et al. 2006; Catania et al. 2008; Davison, So, Goldenberg, Berkowitz, & Gleave 2007; Jenkins & Fallowfield 2000; Jones et al. 2006; Kemeny et al. 2003; Lara et al. 2001; Schutta &
Burnett 2000; Wright et al. 2004). For example, Agrawal et al. (2006) found information about whether the experimental treatment killed cancer cells to be the most useful piece of information for 63% of patients deciding whether to participate in a Phase I oncology study. Similarly, other studies found cancer patients’ hope that the trial offered some medical benefit and belief that it was the best option available to be the most important reasons for CT participation (Catt, Langridge, Fallowfield, Talbot, & Jenkins 2011; Truong, Weeks, Cook, & Joffe 2011; Wang, Tsai, Chen, & Tsay 2011).

Conversely, lack of knowledge about CTs, inconvenience, and perceived drawbacks or risks detracted from patient participation in CTs (Agrawal et al. 2006; Avis et al. 2006; Meropol et al. 2007). Negative attitudes or beliefs about CTs, including patients’ fear of randomization, concerns about the experimental nature of a CT, and lack of therapeutic benefit were some of the main reasons cancer patients declined participation in CTs (Ellis et al. 2001; Jones et al. 2006; Jenkins & Fallowfield 2000; Kim et al. 2008; Meropol et al. 2007; Weckstein et al. 2011). For example, most cancer patients opted not to participate in a CT because they feared their treatment would be delayed or they would receive a placebo if they were to accept CT participation (Ellis et al. 2001; Jones et al. 2006). Also, concern about side effects associated with an experimental treatment was a significant detractor from CT participation as was fear of being a “guinea pig” (Catt et al. 2011; Li, Yu, & Jiang 2010; Sabesan et al. 2011; Wang et al. 2011).

Some of the quantitative studies reported confounding rather than statistically predictive variables that influence patient attitudes or willingness to engage in cancer CTs. For example, awareness and knowledge of a CT has been identified as a strong influence on cancer patients’ willingness to participate in CTs. But greater awareness of cancer CTs has
also been associated with younger age (Jones et al. 2006; Kim et al. 2008), race (e.g., Caucasian) (Meropol et al. 2007), higher education (Kim et al. 2008; Meropol et al. 2007), greater clinical stage (Davison et al. 2007), and higher economic status (Kim et al. 2008).

With regards to education, for example, one study found in a sample of 100 cancer patients that only 23% of patients with elementary education had some general knowledge about the purpose of CTs as opposed to 98% of those with a university or college educations (Jones et al. 2006). Therefore, more research is required to understand the interplay between and among these variables, and to make the link between cancer patient willingness to participate in CTs and actual accrual.

**Limitations of literature assessing personal factors.** What have been lacking in the literature exploring the personal factors influencing CT participation are how personal characteristics or attributes are informed by social and structural level influences, and *vice versa*. Such knowledge will allow investigators to explore and address some of the differences in CT participation found among different races, age groups, and levels of CT awareness. It might also allow some “assumptions” about who is willing to participate in CTs to be challenged, thus potentially addressing recruitment bias.

It should be noted that personal factors are just the tip of the iceberg. The interplay with social and structural factors needs to be understood to avoid an oversimplification of the complex and interrelated array of influences on CT decision-making when addressing accrual challenges. Also, education and decision support related to CT participation could be tailored to address the most important issues, rather than surface-level differences among participants and non-participants. Finally, it should be noted that demographic factors might be just a proxy for underlying socio-political reasons for low accrual in certain populations with
cancer. Education and income level, for example, when explored further, may reveal
differential access to higher education and better paying occupations related to their social
class or cultural group. More in-depth research on cancer patients’ decision-making process
with greater attention and sensitivity to the interplay between socio-political influences is
required. Such attention is crucial for removing barriers and promoting patients’ relational
autonomy in the CT context.

**Social factors influencing accrual.** Socio-demographics such as higher education
(Advani *et al.* 2003; Agrawal *et al.* 2006; Avis *et al.* 2006; Ellis *et al.* 2001) and greater
household income (> $15,000/year) (Advani *et al.* 2003; Agrawal *et al.* 2006) have been
found to be predictors or characteristics of cancer patients who participate in CTs. Other
studies have reported poor CT participation from lower socioeconomic backgrounds and
from marginalized groups (e.g. elderly, women, ethno-cultural) (Advani *et al.* 2003; Brown
& Topcu 2003; Gross *et al.* 2005; Roberson 1994; Robinson, Ashley, & Haynes 1996;
Townsley *et al.* 2005). These socio-demographic factors may overlap with personal factors
identified in the previous section. For example, Lara and colleagues suggested lack of
participation from marginalized groups might be a result of cancer patients’ lack of
knowledge and awareness about CTs (Lara *et al.* 2005). Other studies found patients with
low socioeconomic status have greater severity of comorbid conditions, which precludes
them from CT eligibility (Go, Frisby, & Lee 2006; Gross *et al.* 2005; Kemeny *et al.* 2003;
Kornblith *et al.* 2002). Greater understanding of the structural influences underlying lower
socioeconomic status and the interplay of personal, social, and structural factors impacting
CT accrual is required in order to more fully understand the barriers to relational autonomy
that are disproportionately experienced by these populations.
With regards to relationships that were found to impact cancer patients’ participation in a CT, recommendations received from family members and friends were highly associated with CT participation (Avis et al. 2006; Blackhall, Murphy, Frank, Michel, & Azen 1995; Kim et al. 2008; LaVallie, Wolf, Jacobsen, & Buchwald 2008). Also, altruism or desire to help future cancer patients was among the top predictors of CT participation (Sabesan et al. 2011). Family support for attending clinical institutions hosting CTs also ranks high in importance, particularly for rural or remote cancer patients (Sabesan et al. 2011).

Research has also shown that physicians and their relationships with patients are important factors in patients’ decisions about CT participation. In particular, the trust that patients place in their physicians has been found to be an important predictor of CT participation (Avis et al. 2006; Catania et al. 2008; Coyne, Demian-Popescu, & Brown 2004; Davison et al. 2007; Eng, Taylor, & Verhoef 2005; Jones et al. 2006; Jenkins & Fallowfield 2000; LaVallie et al. 2008; Meropol et al. 2007; Nurgat et al. 2005; Schutta & Burnett 2000). In one survey of 102 cancer patients, 76% reported trust in the physician-investigator as the main reason for taking part in a CT (Catania et al. 2008). Not surprisingly, direct recommendations from trusted physicians have been found by other researchers to be among the most important predictors of CT participation among cancer patients (Avis et al. 2006; Ling Rees, & Hardy 2000; Solomon, Pager, Young, Roberts, & Butow 2003; Baum 1993; Cox & McGarry 2003; Ellis 2001; Flessig, Jenkins, & Fallowfield 2001; Jenkins & Fallowfield 2000; Mancini et al. 2007; Mills et al. 2006; Roberts 2002). These recommendations are even more powerful when physicians have been described as being “overly enthusiastic” or emphasizing the social benefit of taking part in cancer
research (Avis et al. 2006; Flessig et al. 2001; Jenkins & Fallowfield 2000; Llewellyn-Thomas, McGreal, Thiel, Fine, & Erlichman 1991; Mancini et al. 2007). Further research is needed, however, to understand how patients develop trust, whether their trust applies to the treating physician, the physician-investigator, or a third-party researcher, how trust might blur therapeutic and research ethics boundaries, and how trust is maintained across a diverse range of patient populations and social contexts.

In sum, a variety of interpersonal and social relationships help shape cancer patients’ relational autonomy within the context of CTs by providing patients with relationships with trusted individuals that help guide their behaviour, as well as perspectives, opinions, and recommendations that inform their decision making. These social relationships may also practically support rural patients by making CT participation a logistical possibility, thus broadening the scope of options that would otherwise be unavailable for some cancer patients.

**Limitations of literature assessing social factors.** This literature is limited by a lack of appreciation and critical understanding of the interplay between personal, social, and structural factors that influence cancer patients’ decision-making about CT participation. For example, the importance that cancer patients have placed on their physicians’ recommendations as well as the perceived altruistic benefits of taking part in CTs raises the question of whether some patients may feel socially constrained or pressured to participate in cancer research. In particular, the inherently dependent nature of the relationship between patients and their physicians cannot be ignored. The possibility of such undue influence has been raised by Mills et al. (2006), who reported in their meta-analysis and systematic review that “…20% of 100 cancer patients surveyed felt coerced to participate in a CT” (p. 146),
although the authors did not define coercion in their article. Given the difficulties (or uncertainties) in both defining and measuring coercion, caution is required when interpreting this finding in light of how coercion is defined in mainstream ethics. For example, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2nd edition)* identifies coercion as involving a threat of harm or punishment for failure to participate (CIHR 2010). At the very least, Mills et al.’s finding draws attention to the potential for undue influence that may arise when patients are recruited into CTs by individuals in a position of authority (i.e., physicians).

This influence may be very subtle and unintended, stemming from misconceptions held by both physicians and patients. Physicians may believe that certain CTs are particularly beneficial to some patients, which they may convey indirectly in how enthusiastically they present CTs (Avis et al. 2006; Baum 1993; Joffe, Cook, Cleary, Clark, & Weeks 2001). Joffe et al. (2001) found that in their study, physicians who were also researchers focussed more on what CTs may do for patients as a treatment, rather than underscoring the purpose of research is to benefit future patients. From a patient perspective, some cancer patients have identified concern about the impact of their decision about CT participation on their physician-patient relationship and the care they receive (Avis et al. 2006; Davison et al. 2007). For example, Avis et al. (2006) identified the possible change in a patient’s relationship with a healthcare provider as a significant factor that differentiated CT accepters from decliners. In the absence of in-depth interviews, cancer patients’ interpretation of what constitutes undue influence and the role of social structures that empower or disempower patients in the decision-making process (e.g., low socioeconomic status, ethnicity) are not clear. Furthermore, a broader understanding of how macro level issues, such as the structure
and delivery of cancer care as well as availability of cancer CTs, affects the healthcare provider-physician relationship is required.

**Structural factors influencing accrual.** Turning towards structural influences, a variety of factors associated with policies and procedures embedded within healthcare systems and institutions, as well as resource issues, have been identified as important influences on cancer patients’ participation in CTs. For example, uncertainty regarding coverage for costs related to CT participation (e.g., transportation costs, laboratory tests and medication associated with the trial) has been found to have a significant effect on patient accrual in the US (Avis *et al.* 2006; Klabunde *et al.* 1999; Lara *et al.* 2001; Meropol *et al.* 2007). American cancer patients with access to health insurance were more likely to participate in CTs than patients without health insurance (Agrawal *et al.* 2006; Avis *et al.* 2006; Sateren *et al.* 2002). However, study findings differed on whether patients who had access to government-funded health insurance versus private health insurance were more likely to enroll in cancer CTs (Gross *et al.* 2005; Klabunde *et al.* 1999; Lara *et al.* 2001). In Australia, one study found that cancer patients were motivated to accept CT participation because it would allow them access to otherwise unavailable treatments (Sabesan *et al.* 2011). However, whether this was because treatments were otherwise unavailable due to insurance or drug availability issues remains unexplored.

In Canada, among the main reasons patients decided to participate in CTs was so they could access free drugs (Jones *et al.* 2006). However, this was the only Canadian study to uncover access issues. More research is required that examines the Canadian context, given its universal healthcare system and recent reports (Canadian Cancer Research Alliance 2011;
Dent & Yurichuk 2011) that have identified that inequitable access to expensive cancer drugs across the country may be influencing patients’ CT decisions (see Introduction).

Healthcare organizational factors have also been shown to affect the climate within which CT participation is situated. Studies have shown patient accrual is lower in busier clinics and increasingly complex pharmaceutical company protocols have forced institutions to limit the CTs conducted because of resource and staff limitations (Go et al. 2006; Grunfeld, Zitzelberger, Coristine, & Aspelund 2002; Siminoff, Zhang, Colabianchi, Sturm, & Shen 2000; Wright et al. 2004). In addition, decreased access to care and to institutions hosting clinical research has been identified as a major barrier to cancer patients’ participation in CTs, particularly for rural or remote cancer patients (Sabesan et al. 2011). Further discussion of these findings has uncovered how these structural barriers relate back to social factors, such as inflexible work hours, transportation and child care issues, and communication difficulties (e.g. language and literacy) (Gross et al. 2005; Kornblith et al. 2002; Melisko et al. 2005). Applying a relational autonomy lens to this research will elucidate the complex interplay between CT policies and practices and social factors that contribute to some cancer patients’ inability to access CTs within these organizations.

Overall limitations of quantitative literature on CT participation. Overall, this primarily quantitative body of research points to not only the personal nature of decisions about CT participation but also the important socio-political context of cancer patients’ decisions about CTs. While this research has identified important factors associated with CT participation, it has been primarily survey research informed by investigator-developed concepts. As such, it has provided limited understanding of the complex interplay of factors underlying patients’ decision-making process and the experience of making CT decisions
from the patient’s perspective. Without sufficient understanding of how personal, social, and structural factors interact and influence patients’ relational autonomy and decision-making, researchers will be unable to develop targeted interventions to support patients’ relational autonomy and ultimately support innovative evidence-based programs of cancer care.

In the following section I introduce and discuss the contributions and limitations of the qualitative literature as it relates to cancer patients’ decision-making processes about CT participation.

**Summary of Qualitative Literature**

In total, 15 qualitative studies met the inclusion criteria for this review (Table 2.3). Of the 15 qualitative studies, six were conducted in the United States and two were conducted in Canada. Twelve of the qualitative studies used semi-structured interviews and three used focus groups to elicit information from cancer patients about clinical trial participation.

**CT decision-making processes: Findings from the qualitative literature.** In marked contrast to the relatively well-developed body of quantitative literature on factors related to CT accrual, qualitative research exploring the CT decision-making processes of cancer patients has been minimal, with only 15 studies having been conducted to date (Cox & Avis 1996; Coyne, Demian-Popescu, & Brown 2004; Ellis & Butow 1998; Eng Taylor, & Verhoef 2005; Grunfeld, Zitzelberger, Coristine, & Aspelund 2002; Huizinga, Sleijfer, van de Wiel, & van der Graaf 1999; Kohara & Inoue 2010; Kvale, Woodby, & Williams 2010; Madsen, Holm, & Riis, 2007; Mills et al. 2011; Schaefer, Ladd, Gergits, & Gyauch 2001; Schutta & Burnett 2000; Shah et al. 2012; Shannon-Dorcy & Drevdahl 2011; Stevens &
Ahmedzai 2004). This research alludes to the complex interplay between personal and social factors within cancer patients’ CT decision-making.

Most striking in this literature is the important role of family members and health professionals in patients’ CT decision-making processes. Physicians in particular are important because they often provide information about CTs and create a climate of trust in which patients felt comfortable agreeing to take part in research (Cox & Avis 1996; Coyne et al. 2004; Kohara & Inoue 2010; Madsen et al. 2007; Schaefer et al. 2001). Not all patients, however, felt fully informed about the purpose of a CT and its procedures (e.g., randomization), which resulted in feelings of anxiety, uncertainty and distrust among these patients (Ellis & Butow 1998; Madsen et al. 2007). In Huizinga et al.’s (1999) study of 14 Dutch cancer patients, this uncertainty included patients misinterpreting their CT participation as being part of their standard care. Similar findings were reported by Stevens (Stevens 2004), who explored the reasons why British cancer patients declined to participate in CTs.

This body of qualitative research also highlights patients’ concerns about the potential lack of clinical equipoise associated with cancer CTs (Madsen et al. 2007) and

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9 It is not clear in many of these studies whether physicians informing patients about CTs were treating physicians or physician-investigators. This difference may have important implications for patients’ relational autonomy. For example, the dual role of physician-investigators may impact the trust patients have in these physicians and the way in which information was provided, since physician-investigators could have secondary interests that conflict with the patient’s best interest.

10 Clinical equipoise means there is genuine uncertainty in the expert medical community about whether a treatment will be beneficial (Freedman 1987).
the perception that a CT was the only *treatment* option (Cox & Avis 1996; Coyne *et al.* 2004). In one study, interviews with female cancer patients revealed that many expressed a clear preference for the experimental treatment, perceiving it to be more effective than standard care (Madsen *et al.* 2007). As a result, the women felt “forced” to participate in the CT in order to obtain the new treatment. Participants also revealed that they perceived there to be a “moral imperative” for cancer patients to take part in CT research to help future patients and further science (Madsen *et al.* 2007). For some patients who declined CT participation, this sense of obligation was pervasive and led to feelings of guilt (Stevens & Ahmedzai 2004). These findings hint at the moral obligation to promote the social good, or social pressure that cancer patients may internalize as part of the CT decision-making process. Applying a relational autonomy lens to this body of research would help uncover these subtle norms that may undermine rather than support patients’ decision-making process, and that require attention within CT procedures.

Several studies spoke of the role of family members and other support persons in cancer patients’ decisions about CT participation (Coyne *et al.* 2004; Grunfeld *et al.* 2002; Huizinga *et al.* 1999; Kohara & Inoue 2010; Schaefer *et al.* 2001). One study reported “family pressure” as among the main reasons cancer patients gave for participating in a CT (Cox & Avis 1996). The degree to which family members influenced patients’ choices for the patients’ own good (versus the family’s good), how they were involved in the decision-making process, and patients’ preferences with regards to the involvement of their family in CT decisions, however, remained largely unexplored. An exception was Schaefer *et al.* (2001), who found participants carefully considered their social and family responsibilities as part of their decision to take part in a CT.
Summary and limitations of qualitative literature describing cancer patients’ CT decision-making processes. In summary, this body of research highlights the important role of physicians, family members, and support persons on cancer patients’ decision-making about CT participation. However, these studies did not explicitly seek to explore the social context of CT decision making, nor did they uncover any structural influences on patients’ decision-making process. Therefore, more targeted research informed by the theoretical framework of relational autonomy is required that examines to what extent patients are able to exercise autonomy, particularly when embedded in social and political structures, and faced with subtle pressures stemming from both perceived moral and social obligations. In addition, further research is required that explores the actual decision-making process and how cancer patients make the decision to engage in a CT. Within this process, beliefs about CTs that may constrain patients’ relational autonomy and unduly influence their CT decision may be further explored and addressed. Furthermore, a relational autonomy perspective may encourage researchers to consider views from other individuals who are involved in the decision-making process and who are influential from the patient’s perspective.

Treatment decision-making in cancer care: supplementary review of the literature. A related body of literature that informs our understanding of how cancer patients make decisions about CT participation is qualitative research that has focused on patients’ decisions about cancer care. This is particularly relevant given the potential for therapeutic misconception that has been identified by bioethicists (Appelbaum, Roth, Lidz, Benson, & Winslade 1987) in which cancer patients do not distinguish between treatment options offered as part of standard care or through clinical research. Cancer patients’ beliefs about the difference between CTs and treatment is immediately relevant to the previous section on
CT research and the importance of relational autonomy as a lens to guide future research, since this belief may also be influenced by underlying social and political contexts.

**Treatment decision-making processes.** To date, there have been approximately 20 published qualitative studies that have explored the way in which cancer patients make decisions about their cancer care as well as the factors that influence their decisions (Balneaves, Truant, Kelly, Verhoef, & Davison 2007; Charles, Redko, Whelan, Gafni, & Reyno 1998; Davies, Rhodes, Grossman, Rosenberg, & Stevens 2010; Elit *et al.* 2003; Halkett, Scutter, & Borg 2007; Kelly-Powell 1997; Lam, Fielding, Chan, Chow, & Or 2005; Maliski, Heilemann, & McCorkle 2002; Markovic, Manderson, & Quinn 2006; O’Brien *et al.* 2008; Pierce 1993; Pieterse, Baas-Thijssen, Marijnen, & Stiggelbout 2008; Sainio, Eriksson, & Lauri 2001; Sanders & Skevington 2003; Watanabe, Takahashi, & Kai 2008; Wenzel & Shaha 2008; Zhang & Siminoff 2003; Ziebland, Evans, & McPherson 2006). This research has highlighted the iterative and complex nature of the decision-making process, with cancer patients moving back and forth between identifying information needs, seeking information, establishing trust with information sources and healthcare providers, making treatment decisions and evaluating the outcomes of those decisions.

What is striking within these descriptions is the important role patients’ social network, including trusted health professionals, played in their decisions about treatment options. Often, patients reported discussing treatment alternatives with their family members, friends, and fellow cancer survivors as a way of weighing the potential risks and benefits of therapy options, including the possible effects on relationships, ability to carry out their social roles, and overall quality of life (Balneaves *et al.* 2007; Davies *et al.* 2010; Elit *et al.* 2003; Halkett *et al.* 2007; Kelly-Powell 1997; Lam *et al.* 2005; Maliski *et al.*
For many cancer patients, minimizing life disruption for themselves and their families was an important consideration in their decisions, which were described as being “a family affair” (Davies et al. 2010; Kelly-Powell 1997; Lam et al. 2005).

Social networks, however, may not always be supportive of cancer patients’ decision-making processes (Davies et al. 2010; Elit et al. 2003; Maliski et al. 2002; Zhang & Siminoff 2003). For example, in Zhang and Siminoff’s study (2003) of 37 lung cancer patients and 40 family members, some patients reported experiencing pressure from family members to select treatment options that were not congruent with their own preferences. Whether this pressure by family members can be considered “undue influence” and to threaten cancer patients’ relational autonomy in the decision-making process is not clear. Given the interdependent nature of families, as well as the potential emotional vulnerability of some patients at certain points within the cancer journey (Weisman & Worden 1976), making treatment choices that preserve relationships may be as important as selecting a treatment that will enhance survival. There has been limited research, however, that has explored treatment decision making from the perspective of family members and support persons (Maliski et al. 2002; Zhang & Siminoff 2003). The findings from future research may be applied to the context of CTs, and shed further light on how social networks undermine and/or support cancer patients’ relational autonomy in the decision-making process.

Health professionals were also acknowledged by cancer patients as being an integral part of the treatment decision-making process (Charles 1998; Davies 2010; Elit 2003; Markovic 2006; Pieterse 2008; 2001; Sanders 2003; Watanabe 2008; Wenzel 2008; Wenzel & Shaha 2008).
Cancer patients have been found to frequently express the desire to “share” their treatment decisions with their oncologist and other healthcare providers above and beyond the disclosure of information for patients’ informed consent (Charles et al. 1998; Pieterse et al. 2008; Ziebland et al. 2006). This preference has led to a strong movement in cancer care towards shared decision-making, which assumes cancer patients will take an active role in treatment decisions in consultation with their health professionals (Butow & Tattersall 2005; Charles, Gafni, & Whelan 1997; Charles 1999; Wenzel & Shaha 2008). This might mean encouraging health professionals to engage patients’ participation in the decision-making process to the extent that patients want to be involved or directive of their care. However, patients may experience physical, emotional, and relational challenges following a cancer diagnosis. Such challenges may undermine patients’ ability to think clearly about their treatment options and inhibit them from taking an active or participatory role in the decision-making process. Some individuals, at certain times in the cancer trajectory, may prefer a passive role that defers decisions to their physicians (Davies et al. 2010; Degner & Sloan 1992; Degner et al. 1997; Wenzel & Shaha 2008). Other research has uncovered patients describing their medical consultations to be intimidating and “emotionally charged”, with some individuals reporting feeling “abandoned” and “scared” when asked to make a treatment decision, for fear of making a wrong choice (Pieterse et al. 2008; Sanders & Skevington 2003; Ziebland, Evans, & McPherson 2006).

11 For example, in Charles et al.'s study (1998), female patients with cancer expressed appreciation of physicians who explored patients’ understandings of treatment benefits and risks using a ‘decision board’, and helped them to interpret scientific information.
The power imbalances that are inherent in the patient-physician relationship with regards to knowledge and access to care (Say & Thomson 2003) may also place limits on patients’ autonomy in the treatment decision-making process. Contributing to these power dynamics are socio-political factors, such as socioeconomic status and ethno-cultural norms (Lam et al. 2005; Watanabe, Takahashi, & Kai 2008; Zhang & Siminoff 2003). For example, in Watanabe et al.’s (2008) study of Japanese cancer patients’ treatment decision-making preferences, paternalism is a widely pervasive cultural tradition. Japanese physicians are seen by the community to have the indisputable expertise and authority to make treatment decisions without seeking input from patients.

Finally, resource constraints and limited insurance coverage may also inhibit meaningful patient participation in treatment decisions by restricting access to, and thus choice of, provider, treatment, and hospital (Degner 2002; Maliski, Heilemann, & McCorkle 2002). In order to overcome these socio-political barriers and promote patient participation, researchers need to examine the gaps and limitations at the structural level and how these influence patient decision-making (Degner 2002). Such recommendations hold relevance with regards to CT decision making and point to the importance of applying a relational autonomy lens to future decision-making research.

**Discussion**

**Relational Autonomy and Clinical Trial Recruitment**

Guidelines for the ethical conduct of human subjects research demand that researchers are aware of the potential for individuals to be unduly influenced by others, especially by those in positions of authority, which could undermine their ability to autonomously consent to participate in research (CIHR 2010). Researchers have been slow, however, in adopting a
relational autonomy lens when exploring cancer patients’ CT decisions. This is despite growing recognition within the bioethics literature of the significance of social networks and socio-political influences on patients’ autonomy within general healthcare decision-making processes (Donchin 2001; Ho 2008; Mackenzie & Stoljar 2000; Sherwin 1998).

Several studies have identified relational autonomy as being the most appropriate framework to capture the relational complexity of many forms of medical decision making, including advance care planning (Robinson 2011), disclosure of genetic information (Gilbar 2007), and decision-making at end of life (Candib 2002; Eliott & Olver 2008). It is timely to expand the theoretical application of relational autonomy to the unique decision-making processes associated with CT participation, particularly given the difficulties faced by the clinical research community related to accrual and the ethical imperative to ensure respect for research subjects’ autonomy within CT procedures.

Future research informed by relational autonomy theory has the capacity to gain a broader sense of the social and structural influences on cancer patients’ CT decisions and holds the potential to inform policy and practice recommendations, particularly with regards to CT recruitment and informed consent procedures. For example, future study findings may suggest ways of involving support persons in the dialogue about CT participation or addressing socio-political barriers that may exist for some marginalized groups in clinical settings.

Conclusions

While an extensive body of inquiry has described patient attitudes towards, and barriers to, participation in CTs, it has been primarily survey research that has been driven by investigator-developed concepts, which are informed by traditional notions of patient
autonomy. This research is limited in its understanding of patients’ perspectives of the decision-making processes surrounding CT participation and the socio-political context in which these decisions are made. Future research is essential to the development of CT recruitment procedures that are better able to address the barriers to relational autonomy experienced by some patients within their CT decision making and for potentially improving CT enrolment.

Finally, it is important to acknowledge the potential limitations of using a relational autonomy lens to inform research on cancer patient decision-making processes related to CT participation. Supporting cancer patients’ enactment of relational autonomy within the CT decision-making process may not necessarily lead to greater CT participation. In fact, it may lead to the opposite consequence with better-informed and more autonomous patients deciding not to participate in CTs. There is reason to believe, however, that patients who are fully supported in making decisions that reflect their beliefs and values, acknowledge their social contexts, and address the socio-political barriers that exist to CT participation, will feel more empowered to take part in a well-designed CT. This belief stems from research that suggests patients with a decreased sense of personal empowerment and who face socio-political barriers are less likely to participate in CTs (Ellis & Butow 1998; Ellis et al. 2001; Jenkins & Fallowfield 2000; Llewellyn-Thomas 1991). Moreover, there has been suggestion that upholding ethical standards that protect patients’ welfare and interests (such as respect for patient autonomy), and ensuring sound and socially valuable science may contribute to patients’ trust in the research process and their willingness to participate (Weijer & Miller 2007). However, whether or not increased enrolment in CTs is achieved, we must be reminded that a primary motivation for research on cancer patient CT decision-making is to
support patients in making well-informed and meaningful decisions about CTs and to inform the development of enhanced ethical procedures for CT recruitment.
### Table 2.1 – Systematic Literature ReviewsReviewed

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<tr>
<th>Author, date, and country</th>
<th>Focus of the review</th>
<th>Search strategy</th>
<th>Search terms</th>
<th>Dates</th>
<th>Primary inclusion/exclusion criteria</th>
<th># of articles reviewed</th>
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| Biedrzycki BA. 2010. US   | To describe what is known about the factors that influence cancer CT decision making | Pubmed and the researcher’s review of the reference lists in identified articles | “clinical trials”, “patient participation”, “decision making” | 2004 - 2010 | Inclusion criteria:  
• Written in English,  
• Study conducted in the US,  
• Included only adults with cancer,  
• Focused on cancer CT participation,  
• Reported original quantitative or qualitative research.  
Exclusion criteria:  
• Did not have an abstract,  
• Location outside US,  
• Not original research,  
• No cancer CT participation option,  
• Pediatric sample,  
• Sample did not target people with cancer | 16 |
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<th>Author, date, and country</th>
<th>Focus of the review</th>
<th>Search strategy</th>
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<th>Primary inclusion/exclusion criteria</th>
<th># of articles reviewed</th>
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| Cox K; McGarry J. 2003. UK | To explore poor recruitment or non-participation in CT with specific reference to the field of cancer research | CINAHL, Medline, Nursing Collection, British Nursing Index, Embase, Ingenta Journals, Swetsnet-navigator, manual journal searches, internet websites, search of reference lists from retrieved papers | “cancer clinical trials”, “non-participation”, “participation”, “medical research” | N/A | Inclusion criteria:  
- Retrospective descriptive analysis of data from clinical trial non-participants;  
- Follow-up studies of non-participants and focus group studies with potential clinical trial participants  
- CTs outside cancer | 33 |
| Mills EJ; Seely D; Rachlis B; et al. 2006. Canada | The attitudes and barriers of patients to participation in cancer CTs | AMED, Campbell Collaboration, CINAHL, Cochrane library, Embase, ERIC, Medline, NHS EED, Clinicaltrials.gov website, UK national research register | “cancer” or “oncol*”, “clinical trials”, “barriers”, “participat*”, and “enrol*” | Varied according to database. Lower search limit: 1966; Upper search limit: 2005 | Inclusion criteria:  
- Original research study;  
- Contained content addressing patient-identified barriers to participation in cancer CTs;  
- Paper included a semi-structured interview, focus group study, or survey of patients with cancer.  
Exclusion criteria:  
- Only addressed participant descriptions and patient demographics,  
- Vaccine trials | 33 |
| Schmotzer, GL 2012 USA | Investigate barriers and facilitators that | PubMed, CINAHL, PsycINFO | MESH terms: “clinical trials”, “minorities”, | 1995-2008 | Inclusion criteria:  
- Descriptive analysis of data from clinical trial participants and | 22 |
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<tr>
<th>Author, date, and country</th>
<th>Focus of the review</th>
<th>Search strategy</th>
<th>Search terms</th>
<th>Dates</th>
<th>Primary inclusion/exclusion criteria</th>
<th># of articles reviewed</th>
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</table>
| Townsley CA; Selby R; Siu LL, 2005. Canada | Barriers to recruitment of older cancer patients to CTs | Medline, Embase, Cochrane Central Register of Controlled Trials | “clinical trials”, “patient selection”, “cancer”, “neoplasm”, “tumor”, “aged”, “elderly”, “participate”, “recruit”, “enroll” | 1994-2004 | Inclusion criteria:  
• Primary research articles specifically addressing barriers to recruitment of older patients onto cancer CTs,  
• Described strategies to overcome recruitment barriers in an older population | 9 |
|                           | provide explanations for the low participation of women and minorities in clinical trials | “minority groups”, “participation”, “recruitment”, “research subjects”, “neoplasm” | nonparticipants obtained by survey or questionnaire,  
• Focus group studies with potential clinical trial participants and health care providers,  
• Prospective data obtained from health care providers and articles that analyzed the patient recruitment patterns of several studies. Exclusion criteria:  
• Not in English,  
• Did not address research participation or recruitment,  
• Did not represent an underrepresented group (defined as women, ethnic minorities, rural/older, low SES) | | | |
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<th>Data collection method</th>
<th>Factors explored</th>
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</thead>
<tbody>
<tr>
<td>Avis et al. (2006) USA</td>
<td>183 women breast cancer patients</td>
<td>Survey</td>
<td>Telephone interview with investigator-developed and standardized (Davis et al. 1993) survey items</td>
<td>Sociodemographic: age, level of education, race/ethnicity, employment status, income, health insurance, and insurance coverage of the CT Medical: time since diagnosis (self-report), stage of breast cancer, type of surgery, type of treatment, and health (self-report) Knowledge of CTs: purpose of CTs, random assignment, eligibility, participant rights, and informed consent Attitudes towards CTs: beliefs about the benefits and drawbacks of CTs Personal: potential adverse effects of treatment, attitude towards random assignment, trust in medical research, amount of time and travel required, and others’ recommendations</td>
<td>Personal factors • Perception of personal benefits Social factors • Physician recommendation System factors • Time commitment • Travel required • Trial type/phase • Insurance coverage • Cancer center</td>
</tr>
<tr>
<td>Advani et al. (2003) USA</td>
<td>72 African-American and 146 white cancer patients (various diagnoses)</td>
<td>Survey</td>
<td>Standardized 31-item telephone survey (Lannin et al. 1998; Roberson 1994; Ware and Sherbourne 1992)</td>
<td>Knowledge of CTs: awareness and knowledge about CTs, previously asked to participate in a CT; attitudes about CTs; benefits of CTs, Religious and/or spiritual beliefs: fatalism about cancer Satisfaction with their oncologist and clinic: doctor explains things, trust in doctor Financial and/or transportation issues Willingness to participate Demographics: age, level of education, race, household income, participation rates and reasons for refusal Factors affecting CT participation: advice from friends and family, advice from physicians, chance of side effects, chance CTs benefits themselves or others, lack of treatment options, religious beliefs, transportation and cost Functional status: limitations in daily activity, disease stage</td>
<td>Personal factors • Race • Income • Religious/spiritual beliefs (fatalism) • Age • Concern about experimental nature of the trial • Perception of personal benefit Social factors • Physician’s advice • Altruism • Friends or relatives who had participated in a CT System factors • Clinic site • Distance to the clinic and associated travel costs</td>
</tr>
<tr>
<td>Agrawal et al. (2006)</td>
<td>163 patients who had</td>
<td>Survey</td>
<td>Structured in-person interviews using investigator-</td>
<td>Alternative treatment options</td>
<td>Personal factors • Desire to do something to fight cancer</td>
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| USA                     | consented to participate in a phase I cancer study | developed 61-item survey | Pressure to participate, Prognosis, Understanding of protocol, Motivations for participation, Risk/benefit preferences for cancer treatment, Information-gathering behavior, Sociodemographic characteristics, Performance status using the Eastern Cooperative Oncology Group (ECOG) scale | • Education
• Social factors
• family pressure
Significant factors
• education and family pressure (more education related to less family pressure to participate) |
| Baggstrom et al. (2011) USA | 183 patients with non-small cell lung cancer who were eligible for CT based on histology and stage of disease | Retrospective chart review | Investigator reviewed factors associated with declining trials | Demographics: age, gender, ethnicity, insurance status, Medical: histology, stage, performance status, comorbid conditions, eligibility for trial following individual case review | Descriptive factors
Personal factors
• Patient refusal (no other reason given)
• Lack of compliance with therapy
System factors
• Ineligible for trial after individual review conducted
• Lack of transportation
• Distance from cancer centre
• Insurance issues
Significant factors
• No significant difference in characteristics between those who participated and those who declined, including gender, age, ethnicity, histology, stage or insurance status |
| Biedrzycki (2011) USA | 197 patients with advanced gastrointestinal cancer | Survey and retrospective review | Descriptive, cross-sectional research design with one investigator-developed instrument, eight instruments from published research, and medical record review | Sociodemographics: age, education level, race, sex, Disease context: cancer stage, symptom burden, Personal factors: hope, quality of life, preference for research decision control, understanding risks, information, Social factors: trust in healthcare system, trust in healthcare professional | Personal factors
• Age (older patients more likely to accept CT)
• Type of cancer (pancreatic patients more likely to enroll in CT compared to colorectal cancer patients)
In logistic regression, all13 factors of the Research Decision Making Model predicted enrollment when included together
Personal factors
• cancer stage,
• age,
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<td>Catania et al. (2008) Italy</td>
<td>102 patients affected with advanced breast or lung cancer</td>
<td>Survey</td>
<td>Investigator-developed 17-item questionnaire</td>
<td>Demographics: sex, pathology, region of origin, level of education, type of work, living situation, family experience with cancer</td>
<td>• symptom burden, • education level, • race, • gender, • hope, • quality of life, • perceived risks and benefits, • preference for research decision making control, Social factors: • trust in healthcare system, • trust in healthcare professional, System factors • adequacy of research information</td>
</tr>
<tr>
<td>Catt et al. (2011) UK</td>
<td>40 patients who were offered a phase 1 trial</td>
<td>Survey</td>
<td>Descriptive (accepters vs. decliners), one study-specific questionnaire and two standardized questionnaires</td>
<td>Reasons for participating in CTs</td>
<td>Primary reason for participating (given by at least 8% of respondents) Personal factors • Personal benefit • Best treatment option available • Hope • Thought that trial was only option available Social factors • Wanting to help with research System factors • More intensive follow-up</td>
</tr>
<tr>
<td>Davison et al. (2007) Canada</td>
<td>122 prostate cancer patients who had never been asked to participate</td>
<td>Survey</td>
<td>Cross-sectional; investigator-developed 30-item questionnaire</td>
<td>Demographics: age, education, marital status, employment, ethnicity, household income Medical: treatment status, time since diagnosis, PSA level,</td>
<td>Results of Factor Analysis Awareness subscale Social factors</td>
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<tr>
<td>Ellis et al. (2001)</td>
<td>545 women attending a breast clinic for screening mammography or diagnostic assessment plus women with newly diagnosed breast cancer</td>
<td>Survey</td>
<td>Investigator-developed cross-sectional survey, which included the 14-item Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith 1983)</td>
<td>Gleason score, clinical stage Awareness factors: the recruitment process, informed consent, advice from physicians, and altruistic beliefs Acceptability factors: Impact of participation on current treatment preference, potential study side, and randomization Access factors: transportation, time, related costs, age, and influence of family and friends</td>
<td>• Recruitment • Physician advice • Altruism Acceptability subscale Personal factors • Assessment of personal risks and benefits Access subscale Personal factors • Age Social factors • Family and friends influence System factors • Transportation • Costs • Time Personal factors associated with subscale responses • Stage of cancer • Treatment decision • Education</td>
</tr>
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</table>
| Go et al. (2006) USA       | 1012 women and men newly diagnosed cancer patients at community-based cancer | Retrospective chart review | Retrospective chart review | Demographics: gender, age, race, insurance status Protocol enrolment decisions Reasons for not enrolling a patient into a CT: protocol limitation, physician triage, patient decision | Personal factors • Gender (more women than men were found to have CTs available to them; more women than men were enrolled in CTs) • Age (elderly patients were less likely to
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<td>Gross et al. (2004) USA</td>
<td>737 older women with breast cancer who had not yet received radiotherapy or systemic treatment</td>
<td>Case-control</td>
<td>Case-control study</td>
<td>Sociodemographics: patient age, race/ethnicity, zip code, date of trial entry, and method of payment</td>
<td>Personal factors: Residing in high-poverty zip code, Residing in area with high population density, Age, Race, Medicaid, Proportion of county managed care penetration, Proportion of unemployment. Social factors: SES, System factors: Proximity to research centre, whether county had a teaching hospital.</td>
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<tr>
<td>Jenkins and Fallowfield (2000) UK</td>
<td>204 newly diagnosed and relapsed cancer patients</td>
<td>Survey</td>
<td>Investigator-developed cross-sectional design, postal questionnaire</td>
<td>Demographics: age, gender. Medical: cancer site, previous CT experience, previous experience of chemotherapy. Anxiety. Receive information sheet. Accept/refuse CT; trial category. Reasons for accepting/declining to enter a CT</td>
<td>Personal factors: Fear of randomization, Perception that trial is best treatment available, Benefits of trial outweigh side effects. Social factors: Altruism (for both doctor and other patients), Trust in the doctor. System factors: Type of treatment offered (radiation/chemotherapy vs. hormone treatments), More likely to participate in trials with active treatment or placebo than no treatment group.</td>
</tr>
<tr>
<td>Jones et al. (2006) Canada</td>
<td>100 ambulatory cancer patients</td>
<td>Mixed-methods</td>
<td>Cross-sectional design, mixed-methods, semi-structured interview survey</td>
<td>Demographics: age, gender, education level. Knowledge about CTs. History of CT participation</td>
<td>Personal factors: Convenience (other life obligations and extra visits). Social factors: Altruism, Express gratitude for good care and...</td>
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<tr>
<td>Kemeny et al. (2003) USA</td>
<td>77 young and 77 old women with breast cancer and 44 physicians</td>
<td>Case-control and survey</td>
<td>Case-control design, investigator-developed questionnaire</td>
<td>Sociodemographics: age, ethnicity, education, marital status, employment status, education level, household composition, occupation Medical: disease stage, functional limitations, comorbid conditions and depression Planned accrual/actual accrual Reasons for or against participating: treatment side-effects, outcome and cost, research-specific issues, the consent form, their doctor’s and family’s wishes, altruism Physicians’ reasons why their patients had not been offered participation: treatment toxicity, comorbid conditions, one treatment arm considered inadequate, lack of patient support, lack of available transportation, and lack of patient’s understanding of study requirements Physicians’ reasons why their patients had refused participation: treatment side-effects, outcome and cost, research-specific issues, the consent form, their doctor’s and family’s wishes, altruism</td>
<td>Personal factors treatment • Confidence in the study (including confidence in the information and confidence in the physician) System factors • Access to better care and personal benefits (i.e. new drugs)</td>
</tr>
<tr>
<td>Kim et al. (2008) Korea</td>
<td>524 cancer patients who initiated their first cycle of chemotherapy</td>
<td>Survey</td>
<td>Prospective study design, investigator-developed questionnaire</td>
<td>Sociodemographics: age, sex, educational degree, marital status, economic status, distance from clinic, possession of private cancer insurance, religion Medical: diagnosis, disease status Patients’ awareness of cancer CTs and sources of information for cancer CTs Perceptions of patients and physicians associated with the benefits of CTs compared with conventional therapy Patient willingness to participate in CTs Reasons for participating or not in CTs</td>
<td>Awareness of CTs Personal factors • Age • Education • Socioeconomic status • Health insurance Personal factors • Gender • Awareness of CTs • Benefits of CTs</td>
</tr>
<tr>
<td>Klabunde et al.</td>
<td>573 cancer</td>
<td>Retrospectiv</td>
<td>Standardized log sheet</td>
<td>Demographic and clinical characteristics of patients eligible</td>
<td>Personal factors</td>
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| (1999) USA | patients successfully enrolled in non-bone marrow transplant cancer treatment or treatment-related protocols | e review of records | for CT enrollment: facility type, sex, race, insurance coverage, disease status, cancer site, cancer stage, trial phase |  | • Stage of cancer  
• Type of cancer  
• Type of health insurance  
• Time since diagnosis  
System factors  
• Facility type (academic medical centre) |
| Lara et al. (2001) USA | 276 cancer patients | Survey | Cross-section design, investigator-developed questionnaire | Patient characteristics: sex, age, race, insurance status, primary referral source  
CT eligibility: physician triage, protocol availability, patient eligibility  
Patient decision to accept/refuse CT  
Reasons for patient non participation: desire for other treatment, distance from clinic, no reason given, insurance denial, fear of randomization, other | Personal factors  
• Type of health insurance |
| LaVallie et al. (2008) USA | 112 older American Indian and Alaska Native adults | Survey | Cross-sectional design, 37-item survey (Buchwald et al. 2006; Noe et al. 2005) including a hypothetical vignette | Demographics: age, sex, education, current residence, marital status, previous participation in research, telephone in home  
Willingness to participate in CTs: institutional sponsorship, community involvement, human subjects’ issues, and convenience  
Factors that decreased or increased participation: convenience, community involvement, side-effects, friend or family member had this type of cancer, helping the community, informed consent, randomization, chance for cure, family support | Personal factors  
• Threat that confidentiality would be breached  
• Personal experience with cancer  
Social factors  
• Physician with experience treating American Indians/Alaska Natives  
• American Indian/Alaska Native researcher  
• Family support  
System factors  
• Distance to study site |
| Li et al (2010) China | 578 cancer patient-family member pairs | Survey | Two study-specific questionnaires, one for patients and one for family members | Demographics: sex, age, marital status, income, level of education, occupation, religiousness  
Clinical information: time since initial diagnosis, type of primary cancer, disease stage, therapies accepted, Eastern Cooperative Oncology Group performance status  
Experience with cancer clinical trials:  
Attitudes towards clinical trial enrollment: | Personal factors  
• Level of experience with CT in early stage patients (those who participated in a CT and their relatives, those with prior therapy and their relatives, and those who had never heard of CTs and their relatives were more willing to participate)  
• Level of experience with CT in advanced stage patients (patients with prior therapy and their relatives, and patients who had never heard of CTs)  
• Education in advanced patients who failed to respond to therapy |
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<td>Ling et al. (2000) UK</td>
<td>1206 cancer patients referred for consideration of entry into a palliative care CT</td>
<td>Survey</td>
<td>Prospective survey of standardized trial referral forms</td>
<td>Demographics: patient name, age, hospital number, sex, diagnosis and the trial for which the patient was being considered</td>
<td>• Level of experience with CT in advanced stage patients who failed to respond to therapy (those who had never heard of CTs were more willing to participate)</td>
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<td>Factors influencing decision regarding whether an eligible patient was appropriate or well enough to enter a CT: patients’ general performance status, patient understanding of requirements, patients’ likely prognosis and their ability to complete all study procedures</td>
<td>Personal factors</td>
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<td>Reasons stated for eligible patients declining a CT</td>
<td>Social factors</td>
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<td>Reasons stated for eligible patients declining a CT</td>
<td>System factors</td>
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<tr>
<td>Llewellyn-Thomas et al. (1991) Canada</td>
<td>60 colorectal cancer patients with or without metastatic disease</td>
<td>Probability trade-off, survey</td>
<td>Questionnaire followed by one open-ended question. Decision Making Preference Questionnaire adapted from the literature. Two tasks developed from earlier work and adapted to the current study.</td>
<td>Demographic data: age, sex Diagnostic and treatment characteristics: cancer diagnosis, current treatment Preferences for participating in decision making: physician dominant, patient participate Attitudes about CT entry: attitudes towards randomization, preferences regarding the risks and benefits associated with trial treatment</td>
<td>Personal factors</td>
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<td>Social factors</td>
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<td>Mancini et al. (2007) France</td>
<td>267 non-metastatic breast cancer patients invited to participate in a RCT and 1888 patients not invited to participate in a RCT</td>
<td>Survey</td>
<td>Longitudinal design, mailed investigator-developed questionnaires (2, 6, and 12 months after being included in the study); standardized scales measuring depressive symptoms (e.g., CES-D, STAI-8, CASC)</td>
<td>Sociodemographic data: gender, age, marital status, number of children, education, occupation, and perceived economic problems Characteristics upon inclusion of the patient in the study: centre consulted, chemotherapy start date, consultation duration Depressive symptoms Anxiety Social support</td>
<td>Personal factors</td>
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| Melisko et al. (2005) USA | 297 patients with newly diagnosed or recurrent breast cancer and 127 physicians from private and academic centres from specialties of oncology | Survey | Longitudinal design, investigator-developed 28-item questionnaire (patients); 31-item questionnaire (physicians) | Satisfaction with care  
Preferences about decision making: shared or personal  
Willingness to participate in a hypothetical CT  
Reasons for agreement/refusal to be enrolled in CT: randomization acceptable or not, inability to refuse, and altruistic motivations, satisfaction with doctors’ communication | Patient characteristics: year of diagnosis, age, race, educational level, stage of disease, marital status, and family history of breast cancer  
Patient survey factors: access to CT information, safety issues, logistics, confidentiality, attitude toward randomization, and feelings about investigation of complementary and alternative medicine  
Physician demographics: age, practice type, practice setting  
Physician survey factors: impact of CT on clinical practice, costs to the patient, and protocol merit | Personal factors  
- Time for extra tests and visits  
- Concern about loss of control of treatments if in trial and interfere with choosing own treatments (earlier stage)  
Social factors  
- Prefer to wait for physician to introduce about trial (ethnicity)  
System factors  
- Transportation, child care, and income loss (greater for younger women)  
Physicians  
Personal factors  
- CTs stressful for patients  
- Control arm has inadequate therapy  
- Concern about side effects  
- CTs interfere with usual care  
- Lack of information about CTs to provide patients  
- CTs delay treatment  
System factors  
- Enrolling patients in CTs requires extra staff time and adds cost to practice  
- Strict eligibility criteria  
- Clinical trial process slow to answer questions as new treatments emerge |
| Meropol et al. (2007) USA | 137 medical oncologists and 170 cancer patients | Survey | Cross-sectional design, mailed questionnaire; investigator-developed questionnaire informed by the C-SHIP framework (Miller et al. 1999; Miller et al. 1998) | Sociodemographic information: gender, age, ethnicity, and racial group, education level, marital status, employment status, and health insurance status  
Medical practice characteristics: professional setting, board certifications, number of individual patients seen in the past 12 months, number of new patients entered into practice in the | Physicians  
Personal factors  
- Majority believe that patients would benefit from CTs, but community-based oncologists less likely to agree  
- Fear of randomization  
- Lack of patient knowledge about CTs |
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| Nurgat et al. (2005) UK  | 38 patients with advanced or metastatic cancer | Questionnaire | Cross-sectional design, questionnaire adapted from Daugherty et al. 1995 (includes both open-ended and close-ended questions) | past 12 months, number of treatment CTs currently active at a site, number of patients enrolled in treatment CTs in the past 12 months  
Physician interest in participating in treatment CTs  
Physician barriers to CTs: staffing, strict eligibility requirements, financial constraints, time constraints  
Medical history: cancer diagnosis, age at diagnosis, and disease status  
Patient awareness of CTs  
interest and willingness to participate in CTs  
Cognitive-affective barriers to CT participation: uncomfortable with randomization, lack of trust and fear of being a guinea pig, fear of receiving a placebo, fear of side-effects  
Practical barriers to CT participation: logistical barriers (i.e. transportation, access) | Patients  
Personal factors  
• Concern over side effects from experimental treatment  
• Fear of randomization  
• Fear of side effects  
• Race (knowledge of CTs)  
• Education (knowledge and interest in CTs)  
Social factors  
N/A  
System factors  
• Logistical barriers (i.e. transportation to centre)  

Demographics: gender, age, marital status, education, employment  
Medical history: tumour type, previous chemotherapy, previous CT participation  
Patient health status  
Patient expectations about benefits of CT participation  
Quality of life vs long term survival  
Sources of information: when sought more information about illness/treatment options, who patients contacted for more information, satisfaction with amount of information, understanding of prognosis  
Patient comprehension: given informed consent, having understood all or most of the trial information given to them, explanation of trial as research by research team, time to think things over, explanation of reasonable alternatives | Personal factors  
• Perception of personal benefit  
• Obtain more information  
• Surviving as long as possible  
• Obtaining more information about disease  
• Lack of alternatives (phase I vs. phase III studies and patients who previously had chemotherapy)  
Social factors  
• Benefit others  
• Trust in doctors  
• Trust in nurses  
• Altruism  
System factors  
• More monitoring  
• More follow-up and better standard of care  
• Access to better treatment |
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| Roberson (1994) USA      | 8 African Americans, 10 Hispanics, and 10 Native American cancer survivors and asymptomatic individuals | Mixed-methods | Cross-sectional design, investigator-developed telephone surveys (10 items, 7 open-ended) | Patient knowledge and participation in CTs | Personal factors  
  - Lack of information  
  - Fear of being a guinea pig  
  - Mistrust  
  - Ethnic background  
Social factors  
  - Help others  
  - Find a cure  
  - Educate families  
System factors  
  - Assist with medical coverage |

| Sabesan et al. (2011) Australia | 178 medical oncology clinic patients | Survey | Used validated questionnaires from Ellis et al. (2001), for questions about rural factors developed and pilot tested questions, descriptive analysis | Demographics: age, gender, location (determined by postal code), educational level  
Medical history: prior cancers, history of cancer therapy, stage of cancer, previous experience or knowledge of cancer clinical trials  
Patient knowledge of clinical trials:  
Patients’ willingness to participate in a randomized clinical trial:  
Patient’s reasons for participating or not participating in clinical trials:  
Rural factors: inconvenience of travel, cost of travel, loss of work hour, need for family or friends to accompany, need for organizing carers for dependent children and adults, maximum acceptable number of doctor’s visits, maximum acceptable number of blood tests | Reasons for accepting trial  
Personal factors  
  - Personal benefit from trial (66.0% of participants)  
  - Better chance at cure (64.0%)  
  - Any treatment may help me (50.0%)  
  - No other options (36.5%)  
  - Best treatment (34.3%)  
Social factors  
  - Further medical research (70.8%)  
  - Altruism (67.4%)  
  - Family would benefit if they get cancer in the future (62.9%)  
System factors  
  - Receive more information (34.3%)  
  - Access to unavailable treatments (43.8%)  
Reasons for declining trial  
Personal factors  
  - Treatment may be too severe for me (39.3%)  
  - Treatment may be worse on a clinical
<table>
<thead>
<tr>
<th>Author, date, and country</th>
<th>Study sample</th>
<th>Strategy</th>
<th>Data collection method</th>
<th>Factors explored</th>
<th>Factors influencing CT decisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sateren et al. (2002) USA</td>
<td>24,332 patients accrued to National Cancer Institute (NCI)-sponsored cancer treatment trials</td>
<td>Case-control</td>
<td>Combined census data and NCI Surveillance, Epidemiology, and End Results incidence data</td>
<td>Sociodemographics: accrual data: age, sex, race/ethnicity, insurance status, state market penetration by health maintenance organizations, place of residence, income, presence of oncology specialists, presence of hospitals with an approved multi-disciplinary cancer program County data: income, education, poverty, and unemployment</td>
<td>Personal factors: Race Social Factors: Socioeconomic status System factors: Type of medical insurance State of residence Number of oncologists in state</td>
</tr>
<tr>
<td>Solomon et al. (2003) Australia</td>
<td>100 patients with colorectal cancer admitted for surgery at a tertiary center; 43 colorectal surgeons and 103 medical oncologists</td>
<td>Survey</td>
<td>Structured face-to-face interviews with patients using questionnaire developed from previous research and pilot work; mailed questionnaires (to surgeons and medical oncologists)</td>
<td>Patient preferences and willingness to enter a hypothetical CT: willing/unwilling to trade longevity and willing/unwilling to gamble mortality Patient willingness to enter into hypothetical CT Reasons for patient refusal to enter into hypothetical CT: dislike the concept of CTs, dislike idea of randomization, concern with the different size of the operations, concerned with risk of cancer recurrence, risk of complications of one therapy, concerned that quality of life will be too different with one therapy, others will not benefit from the results of the research, treatment given does not offer the best chance of recovery</td>
<td>Personal factors: Type of participant (oncologists more likely to enter a CT than patients and surgeons) Type of surgery (patients) Quality of life (patients) Fear of randomization (patients) Risk of cancer reoccurrence (patients)</td>
</tr>
<tr>
<td>Truong et al. (2011) USA</td>
<td>207 cancer patients and 49 parents of</td>
<td>Survey</td>
<td>Questions modeled after surveys by Daugherty et al. (1995) and the Advisory</td>
<td>Demographics: ethnicity, education, marital status, first language</td>
<td>Personal factors: Poor prognosis (negatively associated with altruism)</td>
</tr>
<tr>
<td>Author, date, and country</td>
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</tbody>
</table>
| Committee on Human Radiation Experiments (1996) | pediatric cancer patients | Medical history: disease status at time of study entry, estimated probability of 5-year survival | Outcome: altruism | **Relapsed/progressive disease (negatively associated with altruism)**  
**Gender (females more likely to be altruistic)**  
**In univariate models, altruism as the motivating reason was associated with phase (phase III), gender (female) age (older), type of respondent (parent), prognosis (poor), stage of disease (relapsed/progressive)**  
**In multivariate models only poor prognosis associated with altruism as primary motivation for trial acceptance**  
**Social factors**  
**Altruism (help other cancer patients or to advance science)**  
**System factors**  
**Phase of trial (phase III more likely to be altruistic compared to phase I) in both univariate and multivariate models** |
| Wallington et al. (2012) USA | 944 patients from safety-net clinics serving largely immigrant Latinos from Central, South, and North America | Cross-sectional survey with quota sampling by age and gender | Information-seeking behavior: from newspapers, magazines, television, radio, the internet, health professionals | Knowledge about CTs  
**Personal factors**  
**Using internet for health information**  
**Education**  
**Marital status**  
**Trust in health information services**  
**Perceived likelihood of developing cancer**  
**Intention to join a trial**  
**Personal factors**  
**Trust in health information**  
**Worry about developing cancer**  
**Information self-efficacy**  
**Knowledge of what a CT is**  
**Social factors**  
**Using cancer information line** |
| Wang et al. (2011) Taiwan | 184 cancer patients | Cross-sectional survey developed by the investigators, based on pilot interviews, investigators’ experience, and published research | Demographics: age, gender, education, occupation, religious beliefs, income, marital status | Willingness to participate:  
**Motivational factors: medical issues, subjective viewpoint, family and friends**  
**Barrier factors:**  
**Personal factors**  
**Medical issues: especially chance of cure**  
**Subjective viewpoint: contributing to medical research**  
**Concerns about adverse effects from clinical trial drugs (barrier)**  
**Patients' past experience with clinical trials**  
**Social factors** |
<table>
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<tr>
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<th>Data collection method</th>
<th>Factors explored</th>
<th>Factors influencing CT decisions</th>
</tr>
</thead>
</table>
| Weckstein et al. (2011) USA | 120 cancer patients who were offered a trial but declined to participate | Survey | Cross-sectional survey developed by investigators based on experience | Needs: Expectations: | • Family and friends’ previous experience  
• Discussions with physicians  
System factors  
• Information from nurses  
Barriers to participating: |
| Wright et al. (2004) Canada | 189 cancer patients, their physicians (n=28), and clinical research associates (n=12) | Survey | Single-institution observational cohort study design; questionnaires with items based on factors from the medical literature and augmented by focus group response | Patient sociodemographics: age, gender, living with spouse, level of education, travel distance to cancer centre, household annual income  
Patient involvement and levels of decision making: to what extent patients are involved in the decision, when the decision is made, factors that influence their entry decision (e.g. perceived personal benefit, when they believed the CRA helped with their decision, helping future patients, supportive of physicians or CRAs, more time spent discussing consent issues)  
Physician, patient, and clinical research associate factors influencing recruitment to CTs: general, trial-specific, encounter-specific  
Patient, physician, and CRA attitudes | Personal factors  
• Adverse effects  
• Fear of randomization  
• Overwhelmed  
• Time  
Social factors  
• Physician recommended not participating  
System factors  
• Cost/no insurance |

**Factors MDs Identified Affecting Cancer Patient Accrual**

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<thead>
<tr>
<th>Author, date, and country</th>
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</tr>
</thead>
</table>
| Kornblith et al. (2002) USA | 156 physicians involved in the treatment of patients with breast cancer | Survey | Cross-sectional design, investigator-developed survey | Physician characteristics: age, gender, ethnicity, medical specialty, the setting of their medical practice, and the proportion of their case load that involved patients age > 65 years  
Physician Survey of Barriers to Accrual: protocol requirements, treatment specific issues, social support, logistic issues, physician attitudes, medical and cognitive characteristics of older patients | Personal factors  
• Comorbid conditions  
• Toxicities  
• Patients not understanding trial  
System factors  
• Transportation needs |
| Siminoff et al. (2000) USA | 147 physicians (107 surgeons and 40 medical | Retrospective review of records; case | Chart reviews and structured in-person interviews with | Chart review data: medical, disease, and demographic characteristics of patients technically eligible to participate in at least one of the phase III breast cancer treatment trials open | Personal factors-surgeons  
• Race  
• Practice type |
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</tr>
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</table>
| oncologists) discussed 245 newly diagnosed breast cancer patient cases (patients eligible to participate in a phase III breast cancer treatment trial) | study        | physicians           | for recruitment                                                                                                                                                                                                     | • % of practice breast cancer patients  
• Cooperative group's support  
• Patient age  
Personal factors-oncologists  
• Practice type  
• Number of hospital affiliations  
• Number of breast cancer patients per year  
• Patient's family history of breast cancer  
• Better prognosis  
• Finding explaining medical uncertainty as part of trials difficult  
Social factors  
• Physician involvement in decision making  
• Patient delay in seeking treatment (surgeons)  
• Patient preference for tamoxifen (surgeons)  
• Patient needed more time to make decision about adjuvant therapy (oncologist)  
• Patient more involved in decision making (oncologist)  
• Discussed chemotherapy only with surgeon (oncologists)  
• Involvement of patient and clinician in decision making (oncologist)  
• Referral patterns (surgeons)  
• Level of patient interest (both)  
• Comfortable talking to patient (both)  
System factors  
• Patient's type of insurance (oncologists)  
• Eligibility criteria (both)  
• Too much paperwork associated with enrolling patient on trial (oncologists)  
• Extra work and expense enrolling patients (oncologists)  

Physician case-based and attitudinal information about adjuvant therapy and phase III CTs  
Physician elicited decision criteria: general history of the patient’s breast cancer illness, examination of the treatment options the physician considered (including knowledge of whether the patient was eligible for a CT and if one was offered), whether there was a discussion of more than one treatment option with the patient, a visual analog scale to rate the strength of the physicians’ treatment recommendations, review of the physician’s rationale for his/her treatment recommendations, items considered (treatment benefits and side effects), decision-making style, final treatment choice, his/her impression of the patient’s reaction to the various treatment recommendations, the physician’s impression of the character and/or emotional status of the patient and ability to understand the information being conveyed, and the physician’s previous treatment relationship with the patient  
Physicians’ attitudes, knowledge, and general practices concerning CTs: perceived barriers to patient participation and their own participation  
Physician sociodemographics and professional characteristics: age, sex, ethnicity, hospital and cooperative trial group affiliations, training, and practice settings |
<table>
<thead>
<tr>
<th>Author, date, and country</th>
<th>Study sample</th>
<th>Methodology and data collection method</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cox and Avis (1996) UK</td>
<td>7 patients (5 men, 2 women) who agreed to Phase I and II trial participation</td>
<td>Qualitative, longitudinal, semi-structured interviews</td>
<td>To explore the psychosocial aspects of participation in early anti-cancer drug trials from the perspective of the patient</td>
</tr>
<tr>
<td>Coyne et al. (2004) USA</td>
<td>17 patients (2 male, 15 female), variety of cancer diagnoses</td>
<td>Qualitative, in-depth interviews</td>
<td>To identify the attitudes and perceptions of rural cancer patients regarding CT participation from the patients’ perspective</td>
</tr>
<tr>
<td>Ellis and Butow (1998) Australia</td>
<td>21 mothers or grandmothers of children attending a local primary school and 20 breast cancer patients</td>
<td>Qualitative, focus groups</td>
<td>To explore the knowledge of, and attitudes towards, randomized clinical trials among women in the community and breast cancer patients</td>
</tr>
<tr>
<td>Eng et al. (2005) Canada</td>
<td>11 men with prostate cancer</td>
<td>Qualitative, semi-structured interviews</td>
<td>To examine the difference and similarities between the reasons for accepting and declining participation in a two-arm active treatment RCT comparing external beam radiation therapy versus cryotherapy</td>
</tr>
<tr>
<td>Grunfeld et al. (2002) Canada</td>
<td>29 clinical research associates or data manager participants</td>
<td>Qualitative, focus groups</td>
<td>To explore the views of clinical research associates on barriers and facilitators to accrual</td>
</tr>
<tr>
<td>Huizinga et al. (1998) Netherlands</td>
<td>14 cancer patients (12 women, mostly advanced breast cancer, 2 men)</td>
<td>Qualitative, semi-structured interviews</td>
<td>To gain insight into the decision-making process that patients go through when asked to participate in a cancer CT</td>
</tr>
<tr>
<td>Kohara and Inoue (2010) Japan</td>
<td>25 cancer patients (mostly colon, lung, breast)</td>
<td>Qualitative (grounded theory), semi-structured interviews and unstructured observations</td>
<td>To reveal the decision-making process in patients considering participation in Phase I cancer CTs</td>
</tr>
<tr>
<td>Kvale et al. (2010) USA</td>
<td>4 older white cancer patients (3 men, 1 woman), variety of cancer diagnoses and stages</td>
<td>Qualitative (hermeneutic phenomenology) open-ended interviews</td>
<td>To explore the experiences of older cancer patients with Phase I CTs.</td>
</tr>
<tr>
<td>Madsen et al. (2007) Denmark</td>
<td>24 female patients with premenopausal breast cancer and 5 patients with advanced ovarian cancer</td>
<td>Qualitative, in-depth interviews</td>
<td>To explore a broader description and understanding of the meanings assigned to patients’ lived experiences during their treatment courses within or outside a trial setting</td>
</tr>
<tr>
<td>Mills et al. (2011) UK</td>
<td>93 men with localized prostate cancer</td>
<td>Qualitative analysis of audiotaped recruitment appointments to an RCT</td>
<td>To explore how patients’ treatment preferences were expressed and justified during recruitment to a randomized controlled trial (RCT) and how they influenced participation and treatment decisions.</td>
</tr>
<tr>
<td>Author, date, and country</td>
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<td>Purpose</td>
</tr>
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</tr>
<tr>
<td>Schaefer et al. (2001) USA</td>
<td>26 women considering participation in a breast cancer prevention CT</td>
<td>Qualitative (grounded theory), conversational-style interview</td>
<td>To describe the process of decision making by women considering participation in a breast cancer prevention trial</td>
</tr>
<tr>
<td>Schutta et al. (2000) USA</td>
<td>8 patients (3 men, 5 women) with various cancer diagnoses who were currently participating in a Phase I CT</td>
<td>Qualitative, focus groups</td>
<td>To explore factors that influence an individual’s decision to participate in Phase I cancer CTs</td>
</tr>
<tr>
<td>Shah et al. (2012) USA</td>
<td>46 patients with localized prostate cancer</td>
<td>Mixed methods, open-ended questions and a questionnaire</td>
<td>To understand patient’s willingness to participate in an RCT comparing intensity-modulated radiotherapy to proton beam therapy.</td>
</tr>
<tr>
<td>Shannon-Dorcy &amp; Drevdahl (2011) USA</td>
<td>25 patients enrolled in early-stage 2 hematopoietic cell transplant research studies and 20 family caregivers</td>
<td>Qualitative, semi-structured interviews.</td>
<td>To examine how patients and their family caregivers decide to participate in hematopoietic cell transplants at a US cancer referral centre</td>
</tr>
<tr>
<td>Stevens and Ahmedzai (2004) UK</td>
<td>22 newly diagnosed breast cancer patients who had declined entry into a Phase III CT</td>
<td>Qualitative, longitudinal, in-depth interviews</td>
<td>To explore the reasons why breast cancer patients decline entry into RCTs of adjuvant cancer therapy</td>
</tr>
</tbody>
</table>
Chapter Three: Methodology

Given the limited understanding of the underlying decision-making processes and the experience of making clinical trial (CT) decisions from the patient’s perspective (see Chapter Two), exploration of how personal, social and structural factors interact and influence patients’ decision making about CTs is required. This involves uncovering the socio-political context of CT decisions, including inherent power differentials and inequities that may unduly influence patients’ decision-making processes. The two empirical studies included within this dissertation are meant to address this gap. The first study, the results of which are presented in Chapter Four, describes CT personnel’s perspectives of the influences on cancer patients’ CT decision-making process and ability to exercise relational autonomy, and best practices to support relational autonomy. The second study, the results of which are presented in Chapter Five, develops a theory of how cancer patients make CTs decisions, which is enhanced by their support persons’ perspectives.

The purpose of this chapter is to describe the methodology and methods used in both empirical chapters. It is divided into the following sections: study design, theoretical framework and use of the literature, study population, recruitment strategies, sampling strategies, interviews, data analysis, validity and reliability and ethical considerations.

Study Design

Two qualitative approaches were used in this dissertation: interpretive description and grounded theory. Qualitative methodologies are appropriate when uncovering subjective experiences as they allow participants to define what is of interest, rather than starting with predetermined concepts or hypotheses, as is typical of quantitative methods (Creswell 1994). However, the use of a priori theory (such as relational autonomy in this study) in qualitative...
research has been encouraged by some methodologists because it provides an initial framework that informs the research question and study design (Morse 2003). In addition to qualitative methodology, a relational autonomy and critical feminist perspective was applied to the analysis. Feminist theory is largely concerned with marginalized persons, particularly the domination and subordination of women in society. A critical feminist perspective encompasses not only a focus on gender but also other sources of social and cultural inequity that encompass both men and women. Moreover, critical feminist theory emphasizes the emancipation of those who have been oppressed and the transformation of oppressive social structures to promote social justice (Kushner & Morrow 2003). It was, therefore, well suited to the objectives of this research study and the ultimate aim of providing a foundation for the development of strategies to enhance patients’ relational autonomy within the CT decision-making process.

**Interpretive Description**

The qualitative methodology guiding the exploration of CT personnel’s perspectives, which is presented in Chapter Four, was interpretive description (Thorne 2008; Thorne, Kirkham & O’Flynn-Magee 2004). This methodology provided opportunities to explore CT personnel’s beliefs about the personal, social and structural influences on cancer patients’ CT decision-making process and how patients exercise relational autonomy. It also guided the categorization of themes related to best practices used by CT personnel to support cancer patients in exercising their relational autonomy within this process.

Interpretive description is a form of inquiry that reveals knowledge relevant to nursing practice. It recognizes the contextual and shared nature of realities, fitting well with relational autonomy theory, where persons are understood as inherently social and
interdependent beings (Thorne 2008). This methodology allows for the identification of themes and patterns from the data in relation to clinical phenomena (e.g., CT decision-making) and for critical interpretation and explanation of the data, as required for a critical feminist analysis of the factors influencing cancer patients’ relational autonomy.

**Grounded Theory**

The qualitative methodology used to construct the findings presented in Chapter Five of this dissertation was grounded theory (Strauss & Corbin 1998). Grounded theory was the most applicable methodology because the goal for this chapter was to develop a theory of how patients with cancer make decisions about CT participation. Grounded theory draws on the tenets of symbolic interactionalism and is an appropriate methodology for exploring decision making and relational autonomy because of its emphasis on change, complex social processes and the active role of individuals and their social networks in shaping the world in which they live (Charmaz 2006). Rather than “discovering” grounded theory, this chapter is more closely aligned with an interpretive approach to theory development that recognizes the social construction of reality “through our past and present involvements and interactions with people, perspectives, and research practices” (Charmaz 2006, p. 10). This perspective acknowledges how research participants’ constructions of reality and grounded theorists’ meanings and views influence the interpretation and building of theory.

Grounded theory provides a set of guidelines (described below, in sampling strategies and data analysis sections) to direct data collection and analysis, generating an overall theory that is “grounded” in the data. This methodology also examines processes; thus, it is well suited to generating an overall theory of patients’ CT decision-making process. Previous health research with cancer patients in the context of complementary and alternative
treatment decision making has also demonstrated the suitability and flexibility of grounded theory in exploring other forms of treatment decision making (Balneaves, Truant, Kelly, Verhoef, & Davison 2007; Balneaves, Bell, Truant, Verhoef, & Davison 2010).

**Theoretical Framework and Use of the Literature**

Glaser and Strauss (1967), the founders of grounded theory, differ in their views on researchers’ legitimate use of the literature and background knowledge in theory development. Glaser does not accept a review of literature prior to developing a theory because it could influence the inductive process of theory emergence, thus increasing the risk of a theory evolving from previous knowledge rather than the data. In contrast, Strauss allows for self-experiences and literature to inform initial understandings of a theory and guide theoretical sensitivity and concepts (Heath & Cowley 2004). Similarly, interpretive descriptive techniques generally discourage the use of *a priori* frameworks, such as relational autonomy, and the extant literature because it can interfere with the identification of themes. However, some have argued that the use of current literature and/or theory to inform an initial analytic scaffold is allowed (Thorne, Kirkham & O’Flynn-Magee 2004; Morse 2003).

Morse (2003) believes including conceptual frameworks such as relational autonomy theory in qualitative inquiry supports the development of new understandings as it provides a “scaffold” for building upon previous assumptions, knowledge and research. Without compromising the validity of a qualitative study, conceptual frameworks allow investigators to acknowledge the assumptions guiding the research, identify known concepts, and inductively fill in gaps in knowledge.

My approach in both the findings chapters is more aligned with Strauss, although I
incorporated elements of Glaser’s approach during the analysis phases as will be described below. In alignment with Strauss, and as discussed in Chapter One, the theoretical lens of relational autonomy was used to explore the ethical dimensions of CT decision making from the cancer patient’s perspective. Relational autonomy theory sensitized me to understanding power relationships and inequalities within the relevant cancer CT decision-making literature prior to embarking upon data collection for the interpretive descriptive and grounded theory studies. This allowed me to determine the scope of the problem at hand, identify known gaps in knowledge, target a study population and appropriately frame my research questions.

I did, however, refrain from returning to the relational autonomy and cancer patient CT decision-making literature when identifying emerging themes and patterns that expanded upon personal, social and structural categories for the interpretive descriptive study. Similarly, when I was developing the grounded theory describing patients’ CT decision-making process and exercising of relational autonomy, I refrained from returning to the literature to further explore emergent concepts. I felt it was important to distance myself at that time so that the theory could emerge and concepts could be related based on the data in front of me. In this way, my methodology became more aligned with Glaser’s approach to grounded theory. In both studies, I positioned myself as open to new meanings – to be found in the data – relative to my initial research questions. However, I did ask additional questions of the data as a result of a relational autonomy (and critical feminist) lens. Cutcliffe argues that the combining of the two approaches (i.e., Glaser and Strauss) in this way can lead to a richer, more complete understanding of the phenomenon under study (Cutcliffe 2000).
Study Population

The initial target populations for this dissertation were breast and prostate cancer patients. This allowed for an exploration of how relational autonomy was differentially enacted by men and women in the CT decision-making process. The primary inclusion criteria were women and men aged 19 years and older diagnosed with breast or prostate cancer and who had been approached to take part in a CT (Phase 0-IV) recruiting through an urban cancer centre in British Columbia. The study location was selected because of its affiliation with the university and also because it is a regional hub for cancer services with multiple trials ongoing. The selection of this centre allowed for a heterogeneous sample since patients travelled from across the province to access services and trials.

The CTs from which patients were recruited were decided on through consultation with the Medical Director of CTs and a Senior Scientist at the cancer centre. Patients were excluded from research participation if they were deemed by CT personnel to be cognitively impaired, too ill to participate or did not speak English.

The decision to broaden the sample to include support persons and CT personnel reflects the guiding theoretical framework of relational autonomy, which recognizes the importance of relationships for patients’ self-determination and exercising of capacities for autonomy. Eligible support persons were any individuals over the age of 19 years who had been identified by patients as being involved or consulted in their CT decision-making process. Support persons could include family members, friends, fellow cancer survivors and primary care providers. Eligible CT personnel were any staff or physicians at the cancer centre who were involved in CT recruitment or management.

For the purpose of this dissertation, 40 patients (see Table 5.1. in Chapter Five) and
11 support persons were recruited. Twelve CT personnel were also invited to participate in order to provide insight into the relational nature of the decision-making process and the best practices that support relational autonomy.

Based on previous qualitative research (Balneaves et al. 2007; Balneaves et al. 2010; Öhlén, Balneaves, Bottorff, & Brazier 2006), it was anticipated that a combined sample of this size would provide the opportunity to explore a sufficient range of decision-making experiences to uncover common patterns and themes and achieve data saturation in which new data do not reveal new codes or concepts or add to the description of existing concepts.

**Recruitment Strategies**

Several recruitment strategies were used to enrol participants into both studies. Nominal financial compensation ($25/interview) was offered to recruited patients and support persons respectively to acknowledge their participation in this study and to cover any related costs (e.g. parking fees).

**CT Personnel Recruitment**

Recruitment began with CT personnel since they were the most accessible population. The Medical Director of CTs and a Senior Scientist at the cancer centre compiled a list of CT personnel and researchers involved in cancer CTs. I approached these CT personnel and researchers via an emailed letter of explanation, consent form and invitation to participate in the study (see Appendix IV and V).

**Cancer Patient Recruitment**

Two graduate research assistants associated with this study (GRAs) were assigned to breast and prostate clinics at the cancer centre that were actively recruiting patients for CTs. Oncologists asked patients if they would be interested in hearing about the study after their
clinical consultation. If patients agreed, a GRA visited the clinic room after the oncologist had left to briefly explain the study and eligibility criteria. The GRA then provided those women and men who were eligible with a study package that included a letter of explanation and consent form, directions to the research office where the interview would take place and a demographic form (see Appendix II, III, IV, V and VI). The GRAs also sought permission to follow up with interested individuals within one to two weeks to provide them time to consider study participation, answer any additional questions and schedule an interview with interested patients. All interested and eligible individuals who contacted the research team (myself or the GRAs) by phone or email were provided with an overview of the study purpose and answers to any remaining questions. An interview was arranged if consent was provided. The GRAs were provided direction with regards to the types of patients to be recruited based on purposeful and theoretical sampling needs (see Chapter Three, Sampling Strategies).

Posters about the study were also positioned in high-traffic areas in the cancer centre, such as public elevators. It was thought that this method of recruitment would be particularly useful for those individuals who had declined or withdrawn from a CT, since these patients might not regularly visit the cancer clinics. The posters, however, were not very successful at eliciting interested patients. Upon reflection, this might have been because the posters were overlooked or because patients who had declined or withdrawn from CTs were not interested in participating in any form of research.

Support Person Recruitment

Patients participating in the study were asked to identify a support person with whom they had discussed their CT decisions. A letter of explanation and consent form (see
Appendix IV and V) were forwarded by email to eligible support persons through the patients and those interested were asked to contact the research team for further information.

**Sampling Strategies**

Sampling and data analysis for both the interpretive descriptive and grounded theory study occurred in two iterative, closely linked phases. For example, in the initial phase of the grounded theory study, purposive sampling was undertaken to select a variety of participants with regards to their CT decision (i.e. acceptors, decliners and withdrawers) as well as type of cancer (breast and prostate). One bladder cancer patient was unintentionally included in the study due to insufficient screening. Her primary disease site was revealed during the interview and the decision was made to incorporate her perspective into the data analysis because her insights elaborated upon other participants’ (breast and prostate patients’) accounts.

Purposive sampling allows the researcher to gather relevant data from diverse groups that will promote a more representative perspective on the phenomenon of interest (Strauss 1998). Attempts were made to recruit patients who represented a variety of backgrounds (with respect to age, education and ethnicity) as these factors may potentially impact relational autonomy and CT decision-making processes (see Chapter Two). A range of CT personnel were also selected based on profession (e.g., oncologist, CT nurse) and gender.

Although my sampling strategy was purposive and focused on a variety of characteristics, I was unable to recruit a balanced number of acceptors, decliners and withdrawers into the study. Initially, the number of acceptors far outweighed the number of decliners and withdrawers that were entered into the study. The Medical Director of CTs and a Senior Scientist at the centre were consulted about this difficulty and they assisted in the
identification of additional decliners and withdrawers who could be approached for the study. With their help, I was able to recruit more decliners but the number of withdrawers remained low. Both breast and prostate cancer patients, however, were recruited successfully into the study.

In the tradition of grounded theory, sampling continues until theoretical saturation is achieved, no new data emerges that is relevant to the identified categories, category development is dense and the relationships among categories are well explicated and validated (Strauss 1998). While theoretical saturation was attempted and achieved in many instances, there were still some concepts that remained not fully saturated due to the limits of the sample and time constraints within the context of a Ph.D. dissertation (particularly, in relation to concepts associated with decliners and withdrawers from CTs).

**Interviews**

All participants were provided a verbal explanation of the study and then given time to reread the consent form and ask any questions prior to providing consent. After signing the consent form, patients were asked to complete a demographic questionnaire to collect baseline data. This included demographic and disease information (e.g., age, marital status, education and cancer type) (Table 5.1).

I conducted in-depth, open-ended interviews (see Appendix VII for interview guide) with each participant (patients, support persons, CT personnel) in space provided by my doctoral supervisor’s (Dr. L. Balneaves) research program. Open-ended interviews suited the qualitative approach because they invite unanticipated stories and statements to emerge that reflect participants’ experiences and beliefs (Charmaz 2006; Thorne 2008).

Given the paucity of research that has explored the relationship between cancer
patients and support persons in making decisions about CTs, individual instead of dyadic or
greater (e.g., triad) interviews were used to collect data about the interpersonal and social
processes through which CT decisions are made. It was felt that individual interviews with
patients and support persons would allow these participants to freely and confidentially
discuss their experiences of CT decision making without creating tension within their
personal relationships. However, recognizing that some patients may feel more comfortable
participating with their spouse, dyadic interviews were conducted with two patients who
indicated a preference to be interviewed with their spouse or support person. These
interviews captured both patients’ and support persons’ perspectives on relational autonomy
within the context of cancer CTs. Previous research supports this interview approach as being
feasible and acceptable to cancer patients and their support persons (Balneaves et al. 2007).
Interviews with CT personnel were conducted separately from patients and support persons
because their questions had a unique focus and there was a shorter time allotted for the
interview.

Interviews were first conducted with CT personnel. These included a series of open-
ended questions that explored how CT personnel understand the concept of relational
autonomy within the context of the CT decision-making and the recruitment process, their
knowledge and experience about why patients do or do not participate in CTs, and
information surrounding best practices to support patients’ relational autonomy in CT
decision-making (see Appendix VIII). For example, CT personnel were asked “Why do you
think patients accept/decline/withdraw from clinical trials?” followed by exploratory
questions related to the institutional context of patient decision making and how patients can
best be supported in their CT decision-making process.
Interviews with patients began with a primary question (“How did you arrive at your decision to accept/decline/withdraw participation in the CT?”) followed by more exploratory questions, including what was important to them in their decision-making process, who was involved and influential in their decision making, and what challenges and facilitators did they experience in making the decision. Patients were also asked how they could have been better supported in making CT decisions (see Appendix VIII).

Interviews with support persons included a series of open-ended questions that explored how they were involved in patients’ decision-making processes, their perceptions of the challenges and facilitators to CT decision making, and their recommendations regarding improvements to the CT recruitment process (see Appendix VIII for interview guide). These questions were important to understand how patients enacted their relational autonomy while situated within social relationship, and how these relationships influenced patients’ CT decision-making process.

As data analysis progressed, questions became more specific to address beginning theoretical conceptualizations and validate suggested relationships and processes. For example, the practice of pre-screening was initially discussed in early CT personnel interviews but it was not yet clear what the practice specifically involved. Therefore, in additional interviews, I gently probed CT personnel further about pre-screening (e.g., “Could you describe what is involved in pre-screening patients for trial eligibility?”). Additional explanations served to validate the relationship between CT personnel’s personal assumptions, structural influences and pre-screening practices that had begun to emerge from the data. These findings were then also probed in patients’ and support persons’ interviews to gain their perspectives on how they experienced pre-screening.
All interviews were tape-recorded and transcribed *verbatim* in order to facilitate close attention and understanding of participants’ responses. Interviews with patients and support persons lasted approximately 60 minutes, while CT personnel interviews lasted approximately 30 minutes.

**Data Analysis**

Transcription and analysis of the data began immediately following each participant interview and was facilitated by transcription services (Transcript Divas) and qualitative data management software program (NVivo 9). To ensure the accuracy of the transcription, the GRAs and I listened carefully to the digitally recorded interviews at places in the transcript where uncertainty was noted by the transcriptionist in what was said. We verified words and clarified meaning, as required. Data analysis was conducted in consultation with my doctoral supervisor. We had regular meetings to discuss transcript analyses and the emerging categories and themes, as well as sampling needs arising from the analysis, revisions to the interview guides, and directions for future data analysis.

**Interpretive descriptive study – data analysis.** Multiple approaches to data analysis are allowed according to interpretive descriptive methodology. Interviews with CT personnel were subject to thematic analysis to uncover patterns of insight about the role of CT personnel in cancer patients’ decision-making processes and to inform understanding of the socio-political context of CT decisions and patients’ relational autonomy. This method of analysis is appropriate for interpretive description methodology that is characterized by a pragmatic desire to generate knowledge about common patterns and themes within human experience (Thorne 2008; Thorne 2000).

To guide analysis, I developed an analytic template for thematically organizing and
analyzing data. Analytic templates are comprised of a list of codes representing themes and relationships identified in the data. According to King (2004), codes can be produced \textit{a priori} based on theory or emerge from the data but all may be modified, deleted or expanded upon as the researcher interprets the data. Prior to developing the template, I read through all the transcripts to get an overall feel for the data. Next, to develop the analytic template, I began the analysis by reading three transcripts line-by-line and highlighting passages that reflected important ideas, themes and examples discussed by the participants. My doctoral supervisor also read the same three transcripts and identified themes. We separately sketched an initial coding framework and then together we asked ourselves what codes and themes could be condensed in order to arrive at a complete analytic template. This process often required us returning to the data to re-contextualize themes in order to understand the relationship between and among codes.

To refine the analytic template, we applied relational autonomy theory to organize major themes according to the categories of personal, social and structural influences. These categories organized CT personnel’s responses to each of our interview questions. The relationships between codes were further conceptualized within the template by posing questions to the data such as “Does this theme fit under this category?” and by paying attention to the context in which the statement was made in order to determine where it best fit within the template.

The analytic template was then applied to the rest of the transcripts. Two GRAs and I concurrently coded the remaining CT personnel transcripts identifying sections of text that corresponded to the template. If an issue emerged from the transcripts as important but the template did not yet cover it, a new code would be added after discussion and agreement was
reached between the GRAs and myself. Initial linkages within and between the data were examined and re-examined for new linkages and organizations. Questions posed to the data to determine the relationships between themes included: “What does this example mean?” and “How is this theme different or related to the other themes?” After reading and separately coding each transcript twice, the template was considered ‘final’ when all the transcripts had been coded and the template was regarded as sufficiently clear and comprehensive. Additional linkages were explored between and among the identified themes and rich descriptions and interpretations of CT personnel’s perspectives were formed (Thorne, Kirkham, O’Flynn-Magee 2004).

**Grounded theory study – data analysis.** Transcripts of cancer patients’ and support persons’ interviews were analyzed using the constant comparative method that is characteristic of grounded theory methodology. The constant comparative method is able to capture social processes and relationships within the data by comparing all “pieces” of data with other pieces until a substantive theory is developed (Strauss & Corbin 1998). In this approach, data collection and data analysis are inextricably linked, with the interview data directing the coding and *vice versa*. Rather than following a linear approach, an analytical framework is developed in which several coding processes occur simultaneously to categorize the data, link the categories, and develop the core category, which is representative of the central phenomenon under study. The ultimate aim is to develop a theory that is faithful to and illuminates the phenomenon of interest (Strauss & Corbin 1998).

I began the analysis by reading the transcripts line-by-line and highlighting passages that reflected important ideas, themes and examples discussed by the participants. This process was supplemented by other analytical strategies, such as asking questions of the data
(e.g., who? what? where? when?), considering opposite or extreme positions to bring out significant properties, and making systematic comparisons between incidents in the data to increase sensitivity to nuances (Strauss & Corbin 1998). Key factors and processes that appeared to influence cancer patients’ CT decision-making processes from CT personnel interviews were also identified and incorporated into the analysis to identify new concepts or relationships. For example, it became apparent early on that the patient-oncologist relationship was important to patients’ CT decision-making processes. Asking further questions of patients’ data, such as “Why was the oncologist-patient relationship important?”, “How was this relationship important to cancer patients?”, “What factors contributed to the importance, or not, of this relationship?”, revealed differences between accounts and illuminated key processes that facilitated this relationship, such as establishing trust and credibility.

I continually questioned the data and strove to develop fitting categories. The aim of this initial stage of analysis, referred to as open coding, is to develop as many codes as possible to ensure “full theoretical coverage” of all important concepts and relationships. As analysis progressed, the codes were condensed into categories that were used to code the interviews in NVivo. This software program supports qualitative data analysis by facilitating the review and coding of the data, the storage of relevant attributes of participants (e.g., diagnosis) and the revision, refinement, and addition of codes (Morrison & Moir 1998). NVivo was also used to search the data for important codes, text, attributes and combinations of such to support the questioning of the data and further theoretical refinement. For example, the data was searched in NVivo using the keyword “trust” and narrowed to breast and prostate cancer in order to explore differences in the experience of men and women in
building trust in the oncologist.

The second phase of the analysis, axial coding, was used to create, test, revise, and modify the associations identified within the data. Axial coding requires the identification of core categories early in the process of analysis that relates to a paradigm model, or a set of pre-defined subcategories that is used to categorize emerging concepts (Strauss & Corbin 1998). Asking questions about what conditions gave rise to each category allowed for organizing the categories of data in relation to each other and identifying properties within the larger framework. For example, questions were posed about the common actions in the codes “wanting access to a specific drug” and “considering health benefits.” This allowed the main category of “Barriers/Facilitators of CT Participation and Withdrawal” to emerge and explain what patients consider when making a decision about whether or not to participate in a CT.

Finally, support person, patient, and CT personnel interviews were linked and important themes identified and contrasted within and across patient-support person dyads and CT personnel perspectives. This more fully elucidated the socio-political context of patients’ decision-making experiences and provided further insight into their relational autonomy within CT decision-making processes. For example, since CT personnel had identified the influence of protocol design (e.g., randomization) and the need to begin the trial within a specified amount of time as a barrier to patients’ CT decision-making process, questions were posed to the patients’ data about these structural influences to explore this aspect in greater detail. Linking interviews allowed for a more comprehensive picture of what factors could be contributing to patients feeling overwhelmed in the CT decision-making process and potentially undermining their relational autonomy.
The final phase involved selective coding. This required the identification of an overarching core category that subsumes all categories and explains the variation present in the data (Strauss & Corbin 1990). Techniques that I used to support the identification of a core category included writing a storyline, using diagramming, critiquing the theory for internal consistency and logic, reviewing the data to complete any poorly developed categories, and validating the theory through discussion with my supervisory committee (Strauss & Corbin 1998). Quite early on I identified the phrase “No man is an island” from a participant interview as an important concept that may be the central phenomenon of patients’ CT decision-making process and relational autonomy. I elaborated on this concept to include “wo/man” so that it was not gender-specific and sought out instances within the emerging theory that might contradict or further support my initial concept identification. On the whole, I was pleasantly surprised to find that the concept was able to explain a variety of personal, social, and structural influences and sub-processes within the model and also fit well with the guiding theoretical framework. It was sufficiently broad to capture a variety of influences on patients’ CT decision-making process yet also retained a ‘self-referent’ (i.e. “wo/man”) for a sense of patients’ personal enactment of relational autonomy. With the assistance of diagramming, I posed questions to the emerging theory such as “Does this process sufficiently capture the experience of CT decliners, acceptors, and withdrawers?” I continued to move back and forth between data collection and analysis until the categories were fully integrated into a substantive decision-making theory.

Throughout both interpretive description and grounded theory data analysis, I paid particular attention to the impact of gender and power on patients’ decision-making processes and relational autonomy. To assist this, a critical feminist lens was employed (see Chapter
One) and questions drawn from both critical and feminist theories were posed to the data (Kushner & Morrow 2003). For example, normative questions that challenge social conventions and traditional ethno-cultural, class, and gender roles were posed to the data, including questions about the relationship of participants to others and to their community and larger society. This allowed for the exploration of any undue influence that may exist within CT recruitment, and more specifically, within patients’ CT decision-making process. In addition, a gender analysis framework was applied to examine specifically how gender may influence cancer patients’ decisions to take part in CTs and how relational autonomy is enacted within this process. Questions posed to the data included:

- How do socialized gender roles differentially influence men and women's CT decision-making processes?
- How is relational autonomy differentially enacted by men and women in the CT decision-making process?
- How do men and women describe power hierarchies within healthcare and larger society and the potential impact on CT decision-making processes?
- How do class, age, and culture influence the effects of gender on the CT decision-making process?
- How do social meanings and expectations related to class and culture influence patients’ abilities to exercise their relational autonomy within the CT decision-making process?

**Validity and Reliability**

The manner in which the validity of qualitative research is evaluated differs substantially from the standards applied to quantitative research. In quantitative approaches,
validity refers to the degree a test or instrument measures what it is intended to measure. However, the truth-value of qualitative research resides in the discovery of the lived phenomenon rather than in the verification of \textit{a priori} conceptions of those experiences (Leininger 1985). The validity and reliability of qualitative approaches can be framed in relation to the procedures of the research process through which the theory is generated, elaborated, and tested (Creswell 1994). The reliability of my research procedures in accessing and accurately representing my study participants’ lived experiences may be demonstrated by my use of theoretical sampling, the systematic approach to data analysis facilitated by the use of a software program, my commitment to filling in poorly developed categories until theoretical saturation is reached, and the range of expertise and theoretical sensitivity of my doctoral committee to support the adequacy of the research process. All procedures used and analytical decisions reached during the research, including the origins and development of major concepts and the identified associations among theoretical constructs, were also made explicit in this dissertation to allow others to understand and critique the analytical logic utilized.

In grounded theory studies, a theory is deemed “valid” if it: (a) “fits” the situation or is faithful to the complexities of the everyday realities that are under investigation and (b) “works” when applied to real world settings (Glaser & Strauss 1967). To ensure the theory “fits” with the data, I employed processes of triangulation and peer examination. Triangulation refers to using two or more approaches to answer the research question, thus allowing for a comprehensive picture of the studied experience (Knafl & Breitmayer 1989). For this dissertation I triangulated my sources of data collection from different participant groups (CT personnel, patients and their support persons) to obtain convergence around the
information gathered. I also triangulated different research methods. I used grounded theory methods, enhanced by interview data from the interpretive descriptive study with CT personnel, to develop the theory “No Wo/Man is an Island”. I also used a critical feminist lens to elucidate the relevant power relationships and any undue influences or gender differences in the findings. Finally, triangulation of investigators occurred within the data collection and constant comparative analysis process. I relied upon two GRAs and my doctoral supervisor to validate the coding process and resultant template. This allowed for discrepancies in coding to become apparent in order to further refine and reach consensus around the interpretation of the data.

Another way to assess whether the study “fits” is to conduct member checks with study participants. Member checking involves testing the theory with informants so they may comments on data, analytic categories, interpretation and conclusions (Lincoln & Guba 1985). Initially, I had thought to validate and extend the study findings using focus group interviews with cancer patients who had participated in interviews and were found to be excellent informants. Preliminary findings would have been presented, along with key aspects of the evolving theory, and participants would have been invited to respond. However, I was unable to conduct focus groups for this dissertation because I had relocated to a different city, which made returning to British Columbia impractical. However, I do not believe this necessarily detracted from the “validity” of the study. Some authors point to limitations of focus groups as a method for ensuring the “fit” of a grounded theory (Charmaz 2006; Sandelowski 1993). For example, Sandelowski argues that participants’ views and beliefs may change over time, thus making their perspectives inherently unreliable (Sandelowski 1993). Also, since the result of grounded theory is one main theory or core
category that describes the various “stories” throughout participant experiences, focus group participants may not recognize their own perspectives within an abstraction of combined perspectives. Therefore, instead of member checking using focus groups, I followed Charmaz’s suggestion that validation may instead occur in relation to developing codes and concepts (Charmaz 2006). For example, emerging relationships between codes and categories were tested in interviews with participants during concurrent data collection and analysis, thereby incorporating member checking into the research process.

I relied on peer review to substantiate the theory and determine whether it “worked.” The findings were shared with my doctoral committee at various stages of analysis. This allowed me to discuss not only the emerging concepts and themes but also the research process and whether my findings were coherent. My doctoral supervisor continually pushed me to consider outlying or negative cases, so that concepts could become enriched and densely described. Any outlying cases that did not fit with the theory were carefully examined to ensure the associated variability was incorporated into the theory. This was important for the representativeness and dense description of concepts in order to offer deep insights about patients’ CT decision-making process (Strauss & Corbin 1990).

The degree to which the theory is perceived by others to provide a useful guide to action (e.g., with respect to decision support interventions) was also assessed by peer examination. For example, the Medical Director of CTs and a Senior Scientist who helped facilitate recruitment at the cancer centre reviewed the diagram outlining the “No Wo/Man is an Island” theory. These professionals interact with cancer patients and families on a daily basis and are well positioned to determine how well the theory could apply to practice. Both professionals provided positive feedback on the model and indicated that the process of
decision making matched their reality and confirmed the theory could be useful from their perspective.

**Ethical Considerations**

Given the focus on cancer patients’ relational autonomy within the context of CT recruitment as a research objective of this dissertation, it might also be interesting to reflect on the ways the dissertation research process may itself have aided participants’ autonomy. There are two examples that I will expand upon here. First, purposive recruitment of marginalized perspectives, such as CT decliners and withdrawers and patients from lower socioeconomic groups, was potentially supportive of their autonomy because it sought to include them in the knowledge generation process. It demonstrated the value of their perspectives and offered these patients the opportunity to engage in meaningful discussion about their experiences. Moreover, the interview process allowed these patients to exercise their autonomous capacities of self-reflection and self-understanding in order to provide responses to the interview questions. A second way the conduct of this study supported patients’ relational autonomy was through the inclusion of support persons. This study affirmed these relationships as important for patients’ autonomy as is recognized by relational autonomy theory, and that family members, spouses *etc.* could be important influences on their decision-making process.

I also abided by other, more traditional ethical recommendations provided by the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (CIHR 2010). For example, approval for the study was obtained from the requisite Research Ethics Board. Interview participants were provided information about the study, assured their participation was purely voluntary, and that their privacy and confidentiality would be respected. Privacy
and confidentiality was particularly important given that patients and support persons may be interacting with CT personnel who were also being interviewed. This was particularly important for CT personnel given the involvement of the cancer centre’s Medical Director of CTs in this study to facilitate recruitment. Confidentiality was assured by assigning all participants an identification number. A master sheet matching names to ID numbers was kept separate from the data in a locked filing cabinet at my supervisor’s research program office. All data was kept confidential and viewed only by the GRAs, my doctoral research supervisor, and myself. All data files associated with the study were password-protected. Explicit care was taken to mask potentially identifying information in this dissertation and in the use of participant quotes. For example, the specific geographical location of patient participants was not named.

Subject matter of the interview may have been emotionally distressing for some patient and support person participants. As such, information about supportive care services at the cancer centre was provided during the informed consent process. Care was also taken to pause during the interview if the participant appeared distressed. For example, if the participant became teary I then offered to stop the interview completely or, if the participant desired to continue, I gained reassurance that he/she felt emotionally ready to continue. Patients, support persons, and CT personnel who participated in the study were invited to leave their contact details on the consent form to receive a copy of a lay summary of the study findings.

Disseminating the knowledge obtained from this study so that it may be useful and advance the field is a key ethical concern of mine. Reports of this research project will be prepared for dissemination at conferences and health forums focusing on research ethics and
cancer care. Publications will also be prepared for peer-reviewed scientific journals to disseminate the findings to an international audience as well as a variety of health professions. An executive summary of the findings has already been shared with the NCIC CTG at their annual spring meeting in 2012 (attended by researchers, CT personnel, and pharmaceutical industry representatives from across Canada). I, along with Dr. Balneaves and Dr. Richardson from the current study’s CIHR grant, were successful in obtaining a CIHR Meetings, Planning and Dissemination grant to conduct an interactive workshop with key CT stakeholders (i.e., patient advocates, researchers, administrators, and pharmaceutical industry representatives) and research ethicists at the NCIC CTG annual spring meeting (co-sponsored by the NCIC CTG Quality of Life Committee). The primary goal of the workshop was to provide efficient knowledge transfer of study findings and to discuss future research projects that may further test the developed theory in other clinical sites and cancer populations across Canada. In addition, the workshop provided a venue to begin brainstorming potential decision support strategies that will aid patients in exercising their relational autonomy within current CT procedures in cancer care. A summary of the workshop outcomes is in development and will be distributed throughout the NCIC CTG network and the larger international cancer CT community (e.g., National Surgical Adjuvant Breast & Bowel Project).
Chapter Four: Cancer Patient Accrual to Clinical Trials: A Qualitative Analysis of Clinical Trial Personnel Perspectives

Low accrual to cancer clinical trials (CTs) continues to challenge the translation of innovative research into clinical practice to improve cancer patient outcomes. Much quantitative literature has described barriers to cancer patient accrual to CTs. However, CT personnel perspectives, including oncologists and CT nurses, have informed little of this literature. When a trial opens at a centre, treating oncologists who are also part of the research team are often responsible for identifying eligible patients and making initial contact with them about the trial. If patients are interested in the trial, CT nurses will often then conduct the initial consent process. However, both CT nurses and investigators/oncologists may review the trial protocol with patients, discuss medical information with patients and discuss the intervention/drug and potential side effects. They will also review the time commitment and other logistics required for the trial. Both CT nurses and investigators/oncologists are also available in person or via telephone to answer any additional questions and concerns patients might have while they are making a CT decision or once they are enrolled in the trial.

CT personnel are uniquely situated to possess knowledge of the larger CT and cancer care system (i.e., structural context) while also having insight into cancer patients’ personal and social situations that may impact CT decisions. Moreover, CT personnel often have close relationships with patients and are highly influential in their CT decisions (Avis et al. 2006; Joffe et al. 2001). Therefore, understanding CT personnel’s beliefs about what influences patients’ CT decisions is important since their beliefs may impact how they discuss and share trial information with patients. Finally, an exploration of CT personnel’s experiences allowed
for more patients’ perspectives to be represented in the overall research, since CT personnel were involved in recruiting patients with multiple tumour types, and from different socioeconomic status and ethnicities, to CTs.

The purpose of this interpretive descriptive study was to gain comprehensive understanding of the personal, social, and structural influences on cancer patients’ CT decision-making. Interviews with CT personnel included open-ended questions that explored the challenges and facilitators experienced by cancer patients in making decisions about CTs and how health professionals could better support cancer patients and their support persons in the CT decision-making process.

Twelve cancer CT personnel were interviewed for this study, including six nurses and six oncologists involved in multiple aspects of cancer CTs (e.g. patient recruitment, enrolment, and management of CTs). Half of the participants were female (n=6) and the rest were male (n=6). CT personnel were not tumour site specific; they were involved in trials related to breast, prostate, gynaecological, gastrointestinal, head, and neck cancers.

**Findings**

This interpretive descriptive study used thematic analysis guided by a relational autonomy lens to structure the CT personnel findings according to the personal, social, and structural influences on why cancer patients accepted, declined, and withdrew from CTs. Quotes from the interviews with CT personnel are used to illustrate major findings where appropriate.

**Personal Influences on Patients’ Decision-making**

CT personnel believed cancer patients’ personal beliefs about CT research played a major role in patients’ decision making about CTs. As one participant shared, “the vast
majority of patients have internally-driven beliefs and values that would contribute to the
decision to go into a clinical trial.” Personal beliefs included beliefs about the potential
benefits of the intervention being tested in the trial or general beliefs about what it means to
participate in CTs. In addition, both CT nurses and oncologists thought patients’ hope, fear,
anxiety, and distress informed their personal beliefs and decision making related to cancer
CTs. The following sections elaborate on these themes in greater detail.

**Patients’ beliefs that they will receive better care.** CT personnel thought the
primary reason why cancer patients accepted CT participation was because of their belief that
trials will benefit them directly by offering them a new curative treatment option, a treatment
that could prevent the cancer from recurring, or a treatment that could offer them fewer side
effects or better quality of life. CT personnel also noted that some patients might have a
desire to try something different, which is often connected to their belief that “newer is
better” and that CTs are at the frontier of medicine and offer the best and most advanced
treatments. As shared by a medical oncologist:

> So I think the number one reason is because they want to have something that will
benefit them. Obviously they want to try something different or they want to do
something different, they want to do something new. So many trials are geared
towards patients that don't really have other options. Or the current options, we know
what they can do and so some people want to try to do something better than or try to
get the best care as they can. So they want to try to benefit themselves.

CT personnel believed that patients’ perceptions of personal benefit superseded altruism as a
motivating factor for CT participation, although benefiting future populations was also
perceived to be an important consideration. As a medical oncologist stated, “I will admit
there’s probably the rare patient who is probably truly altruistic but ultimately most patients
say, ‘Well, what does this mean for me?’” Later in the interview, the same participant
remarked “So, in the end, it always comes down to, as much as we say, ‘You’re helping the population’, people do it for themselves.”

**Patients’ beliefs about being a “guinea pig.”** Patients’ concerns about the quality of care and the unknown risks posed by a CT and being “experimented” upon, with negative consequences, were raised by CT personnel. CT personnel believed some patients associated CTs with being a “guinea pig”, which was perceived to negatively influence their perspective of CTs and the CT decision-making process. One oncologist shared how he thought patients’ concerns about being the subject of an experiment might stem from misunderstandings about the nature of CTs and research in general: “I think it could be just a lack of understanding of what a clinical trial is and they hear the word “research” and they feel like they’re a guinea pig.”

Other CT personnel perceived some patients to be worried about not receiving the best care if they are in a trial. This belief may be tied to the age of the patient, as one CT nurse recounted the views of her grandmother towards CTs:

> I think of someone like my grandmother, for example, who’s just, ‘Well, I don’t want to be someone’s guinea pig.’ She looks at it that way, that she’s not going to get good treatment if she’s on a study but she will if she – just as a regular patient.

The same nurse described how it is important for CT personnel to communicate information to patients so that they understand they will still receive good care while on a trial and can provide informed consent:

> I think some [patients] think that it’s an experimental treatment, or they don’t understand that they’re still going to get a proven treatment on it. And a lot of people think, ‘Oh well, research is either you get the placebo or the real drug’ and they’re like ‘Well I don’t’ – They don’t understand or maybe they haven’t been given enough information that here’s your options, here’s the treatment you will get, or on a trial you’ll get this treatment plus this and this and this. So maybe they’re not shown the benefits of it.
Historical considerations were also perceived to play a role in patients’ understanding of and their beliefs about CTs. One nurse imagined that patients who had immigrated to Canada might be particularly concerned about being used for experimentation if their home country had a history of mismanaging research:

And it could be too, you know, I’m just supposing too, if they’ve come from another country where perhaps research or experimentation on humans, it wasn’t terribly well managed at some point, they may have these particular components.

**Hope for a benefit/fear of risks.** Emotions were identified by CT personnel as having a powerful impact on patients’ decisions to participate in CTs. CT personnel believed that many cancer patients persistently held hope that a trial would benefit them despite being informed that the treatment may not be individually effective. As one CT nurse remarked:

There’s a hope that somehow this may be a wonder drug that may do it for them and so they’re willing to put up with all the other things, you know, even though it’s pretty clear – it depends on the drug.

In contrast, anxiety or fear of cancer growth or recurrence was also perceived to motivate patients to participate in trials. As one radiation oncologist explained:

They [patients] have a hope to get the best treatment, right? Or a hope to get the least side effects or a hope to be cured, you know? Or a fear or the flip side to all of those, the fear of not being cured, or a fear of not getting the best treatment.

Hope for better outcomes or fear of illness progression was perceived to exist on the same continuum and to differ according to disease stage. CT personnel shared their belief that heightened emotions can sometimes interfere with patients’ understanding of the purpose of CTs and their CT decision making. This was believed to be particularly the case for patients with cancer recurrence or those who had advanced disease, where hope was seen to gradually transform into desperation or fear. This was perceived to contrast starkly with other
cancer patients, who felt hopeful about their prognosis but willing to consider alternatives to usual care.

One CT nurse described the quandary of advanced cancer patients who had already exhausted several lines of chemotherapy and were now faced with limited to no standard treatment options. With nothing else to try, these patients were seen as being motivated to consider CTs because they are “at their wits end” and were facing huge risks to their mortality. As another CT nurse remarked, “patients are quite keen to continue because they don’t want to let go, they want to continue on treatment.”

Other CT personnel believed some patients were more motivated by fear of recurrence because their initial diagnosis and treatment was so traumatic:

They’ve been frightened to death because of this diagnosis of cancer. Often they’ve had their surgery and really at surgery, you’re cured. And anything else beyond that is just to ensure that if there’s anything small that’s out there that we can’t see, we can hopefully get rid of, so that’s what radiation and chemotherapy is for. So those people have been petrified and they want to do everything that they possibly can to make sure that they never have to face it again.

**Anxiety and lack of understanding.** CT personnel reported that cancer patients were often concerned about potential toxicity or side effects from the drugs being tested in CTs and some decided not to participate in a trial after learning about the risks. As shared by a medical oncologist:

One of the unknowns is the toxicity. It has not been well worked out many times and so they're concerned about the additional toxicity or other toxicity, side effects that might happen from a clinical trial drug.

CT personnel could appreciate patients’ fears, particularly in relation to Phase I trials, in which there is limited knowledge about the intervention at this stage of testing. However, CT personnel expressed concern when cancer patients’ anxiety was seen to interfere with their understanding of CTs. Without guidance from a health professional or adequate
information and emotional support, one oncologist believed the decision-making process could be totally overwhelming for some patients, thus demonstrating the importance of social relationships for supporting cancer patients’ capacities for autonomy:

Yeah, so some people can’t get their heads around flipping a coin and being randomized or the inhumanity of a coin or a computer deciding their fate and treatment, rather than the doctor who’s in front of them or at least somebody human. And they just can’t get their head around the business of randomization at all. Do what’s best for me, you know, I can’t decide, there’s too much pressure, there’s too much stress, there’s too much at risk to go that way.

CT personnel believed that patients who were deciding between multiple treatment options, without a clear sense of which to take, also experienced anxiety and perceived the presentation of a CT as distressing. Newly diagnosed cancer patients were observed to be particularly vulnerable since they were also dealing with the trauma of receiving a cancer diagnosis while being inundated with treatment information. As one medical oncologist stated:

A lot’s coming at them. Sometimes it's their first treatment for cancer and so a lot is coming at them. So I think the understanding of the whole picture, the bigger picture or the little picture, the details, is difficult. So that's what makes it most difficult.

**Inability to cope with logistics.** The majority of CT personnel referred to the significant time commitment required of patients to participate in CTs. They believed this commitment discouraged many patients with early-stage cancer, with most viewing CT participation as a “hassle”, especially when there was no sense of urgency to enter the trial. As one oncologist remarked, “they look at all the things that you have to do, all the extra tests and they just don’t want to do it.”

Cancer patients were perceived to withdraw from trials because the logistics associated with their participation became too burdensome. As one CT nurse commented, patients realize after they have agreed to participate “that [it’s] just too much of an
inconvenience for them.” As another CT nurse explained, “they just don’t like the amount of travelling, visiting and everything in order to participate on the trial. So that would be the main one.”

CT personnel appreciated the relational aspects of trial participation, with patients needing to coordinate with family to help them attend CT appointments. CT nurses pointed to the difference between what patients expect when they sign up and the reality of participating in the trial, especially when travel to the study site and coordination with their social network was required:

So especially patients here, especially oncology patients, they’re just not up for maybe that extra ECG they have to do, or extra scan that we may require for this particular trial. It is time consuming, so they may not be – they may have been eager to join up, but when the reality of – especially if they don’t live in the city and they’ve got to come in and maybe they’re staying at someone’s house and the parking and they’re – you know, a lot of them too don’t like coming into [the big city], it’s busy and scary for some people to come into a city.

These findings call into question the effectiveness of informed consent procedures meant to inform patients about what is needed to partake in studies; however, the last quote also hints at the social and structural context of trial participation (e.g., staying as someone’s house, parking, etc.). Broadening the informed consent perspective using a relational autonomy lens appreciates the social and structural context of trial participation on patients’ CT decisions and their informed consent.

Finally, other CT personnel believed patients accepted trial participation but then later withdrew because their condition worsened and they found it too difficult to cope with the demands of the trial because of fatigue or other cancer-related symptoms. As one CT nurse shared:
Sometimes if things go wrong, like the disease starts progressing and they’re having to travel from [distant city] all the way to here for scans and blood tests and doctor’s visit, it tires them out a lot. So I’ve had a couple of patients withdraw because of that.

**Social Influences on Patients’ Decision-making**

In addition to personal factors, CT personnel also identified social factors that they perceived to influence cancer patients’ CT decision-making. Altruism, trial presentation by the physician, and family opinions were the key social influences identified as impacting patients’ decisions to participate in CTs.

**Altruism.** Although CT personnel perceived the majority of cancer patients to be motivated to participate in CTs because of their own self-interests, some individuals were perceived to be influenced by the desire to “give back” and help further science to benefit future cancer populations. Concern for society and important relationships, especially concern for the future well-being of their family, was perceived by one radiation oncologist specializing in prostate cancer to be an influential factor in some cancer patients’ decisions to participate in CTs:

Patients want to contribute, especially in my practice, they’re often older men who’ve got young kids and they genuinely want to do what they can so that if the younger generation gets prostate cancer, they can do better than they’re doing.

A few CT personnel shared experiences of consulting advanced cancer patients who were excited about participating in a CT in order to help science find a cure for the disease. These patients were perceived to make a quick decision without much thought as to how participating in the trial would impact them personally or socially. As part of the informed consent process, CT personnel described how they sometimes discouraged cancer patients from considering what the CT can do for others. Instead CT personnel re-oriented patients to reflect on how participating in the CT could impact their own situation. CT personnel thus
appeared to be privileging patients’ individual autonomy over their relational autonomy in these cases. However, CT personnel may actually be acting pragmatically and out of concern for the possible consequences of patients not considering the individual impact of CT participation, which could be their withdrawal from the trial. One CT nurse explained:

A lot of people say yes to clinical trials because they feel like they are doing a service to humankind. I often say to people, look, you cannot view this as you are doing a service to someone. You really have to think about what this commitment’s going to be for you and it’s nice that you want to help others, but you have to be able to do all that’s required and if you can’t, because it’s getting in your way, or you’re too tired to make all these appointments then you’ve got to keep that in mind. You’ve got to think about that.

**Presentation of trials.** CT personnel described the presentation of the trial by the physician, or what many CT personnel referred to as the trial “sales pitch”, as influencing cancer patients’ decisions about CT participation. When asked to describe the pitch, many CT personnel related the process to the selling of a car. However, CT personnel emphasized that unlike selling cars to make personal profit, the oncologist was perceived by his or her colleagues to be presenting the trial with the patient’s best interest in mind:

Like I say, the oncologist may think that in some cases, it just gives the patient more options for future treatment and sometimes – and how it’s presented, I think may… First, do they think it’s in their best interest? Well, obviously they wouldn’t present it if it wasn’t.

Sometimes, however, CT personnel believed physicians’ personal convictions about a trial could become apparent in the trial discussion and inadvertently sway patients’ attitudes and decision making. If physicians, for example, were questioning the science of the trial or whether the trial was a good option for the patient, their unease may become apparent in the consult. CT personnel thus demonstrated an awareness of the relational nature of CT recruitment and the power held by physicians to influence patients’ CT decisions. As one radiation oncologist shared:
I mean, you might be doing a study that involves pushing the radiation program harder to treat prostate cancer but as a clinician, you’re also rather worried about the toxicity. So when you present this study to the patient, your fears and anxieties about the study are evident and if that comes over, then the patient is more likely to decline the study.

While many CT personnel believed oncologists try not to pressure or influence patients’ decision making, some CT personnel recognized that subtle communication factors such as “the way the trial is presented to the patient, the body language and the terminology used” might encourage patients to privilege one option over others. Many CT personnel suggested that physicians may not recognize their own communication nuances and how this might sway patients. As a radiation oncologist explained, patients may not be aware of the ways in which physicians’ subtle conveyance of their personal beliefs can influence their decisions:

It’s [communication] really subtle and they [doctors] may not even recognize it’s going on themselves. In fact, I’m sure most of them don’t. It really isn’t often somebody comes and says, well, this doctor said this to me.

Another radiation oncologist provided a telling example of subtle communication, demonstrating how the way things are phrased could influence patient decision making about CTs:

For example, we’ve got a great trial here of an extra high dose boost of brachytherapy [internal radiotherapy] for prostate cancer, and all of us who are doing the trial in our hearts believe that it will likely give better cancer cure rates, at a cost of more toxicity. The trial basically comes down to the trade off, if we’re right between curing a few more people at a cost of more toxicity. So there you see, you could present that trial as, ‘We’ve got this great new treatment which we think, but we have to prove it with a study, is going to cure more people.’ Sounds great! Or you could present, ‘You’ve got this trial which is looking at this new treatment but we’re pretty sure it’s going to have more side effects, and most men with prostate cancer don’t die of prostate cancer, they die of old age, and so if you participate in this study, you may just get all the side effects.’ You could say something like that, so I think those are the subtle ways in which it’s presented.
A few CT personnel did share the concern that if a physician was an investigator on a study, he or she might experience a conflict of interest. This conflict was associated not only with the pressure to accrue patients to the trial, but also with the scientific rewards of achieving the targeted sample size and recognition from funders and peers. As one radiation oncologist explained:

Investigators have a lot invested sometimes in trials. Sometimes it is about the per case money to keep their clinical trials’ program going. I’m not pointing a finger at Dr. X, okay. That’s not what I mean to do here but all of us, right and also another investment will be…I mean, there is some recognition if you put patients on trial. Flip side is, you know, people rain on your parade if you don’t put patients on trial. So there’s pressure there.

**Trust and preservation of the physician-relationship.** CT personnel perceived patients’ trust in their doctor enhanced their receptivity to subtle clues or encouraged patients to follow their physicians’ recommendations related to CTs. One radiation oncologist elaborated on how patients’ trust in physicians was implicated in their decision-making:

I think it’s the trust in their doctor […] and if it’s a randomized trial between two different treatments, I think it may come down to how the standard treatment is presented and how the experimental treatment is presented to the patient in terms of potential benefits and side effects […] I think patients appreciate the honesty that comes across, that builds the trust and then they’re more likely to do what you recommend.

CT personnel also reflected on the possibility that some patients were accustomed to deferring to physicians in the treatment setting and might interpret the invitation to participate in a CT as itself a recommendation, even if the oncologist has taken precautions to present the trial impartially. This may reflect the power dynamic between physicians and patients, where patients accepted the advice of their physicians because they were perceived to be the expert or authority. As one oncologist shared:
They [patients] see [it as] an authoritarian thing and they don’t think it and then they’ll find it easy to go on, cause they say if the doctor mentions it, it must be good. So it becomes almost an authoritarian thing or they’ll just say yes to it.

Other CT personnel discussed examples of patients who appeared to make decisions out of a desire to please their physician or to preserve their relationship with their physician or the cancer agency. One oncologist commented on how patients may make CT decisions so as not to compromise care they receive from their physician:

Some patients actually stay on trial because they’re worried we’ll get upset at them and then not give them any more treatment and I really try to emphasize we are not like that at all, which is – it’s kind of sad that they think of us that way. And I think it’s more of a fear. I don’t think they see anything horrible of physicians or the clinical trial’s process, I think it’s just a fear that, if they say no to something, then I’ll be upset, not give them chemo any more. I’ve actually had a few patients tell me that. I’ll say, ‘Where did you get that idea from?’ And they’re, like, ‘I don’t know.’ Because I never said that. And, yeah, patients just have that fear sometimes.

This misunderstanding by patients about what was communicated by physicians was believed to arise from the fear or distress associated with the cancer diagnosis rather than the hierarchical patient-oncologist relationship. As one oncologist explained, it matters less how well physicians present all the options because patients will hear what they want to hear in their time of need:

I think the patients themselves are going through so much with the diagnosis so you mention one thing and all they hear is ‘Wah, wah, wah, trial, wah, wah, wah, wah. I think it’s a good idea.’ And so then they end up hearing, ‘My doctor thinks this is a good idea if I do this.’ Right? And they don’t hear everything else.

**Socioeconomic factors.** The complexity of CTs and the consent process was perceived to pose a barrier to informed decision making for certain patients. CT personnel perceived patients’ educational background or “cultural differences” affected their ability to understand CT information. Additionally, language barriers and literacy were thought to limit
patients’ understanding of CT information. As shared by a medical oncologist and another CT nurse:

It's very medical and scientific and a lot of people just don't understand. And in my patient population, which may be different from others, a lot of these guys are older, 'cause it's prostate cancer, and sometimes when I'm talking to them, I don't know if they really understand what the implications are and so on. Maybe they don't understand the details. I think they understand the big picture but I think sometimes it's difficult about the details.

Illiterate […] you do get people that are illiterate that will make a snap decision and think that they don’t need to read or they won’t ask for someone else to read it to them because maybe they’re embarrassed.

Other CT personnel believed “general social issues” made it difficult for patients to participate in CTs. For example, lack of income confounded with geographical distance were perceived to be significant barriers to patient participation in CTs, since patients may not have the money to pay for travelling to and from the trial site. As one participant stated, “high risk population, like low income, that would be an issue because even transportation to them is a huge factor for compliance.” These beliefs about socioeconomic factors led to CT personnel forming assumptions about patients’ abilities to participate in CTs. For example, one radiation oncologist spoke about how geography was linked to socioeconomic resources and how his assumptions about a patient’s occupation and financial resources influenced his decision about whether or not to present a trial to this patient:

You can tell a lot about whether it’s going to be a fit also on incorporating where they live and what they do. I mean, obviously a logger who lives in [city up north], you can just guess he’s not going to have extended health benefits to bring him down so I look at things like that…So definitely geography, that’s a huge piece.

**Gatekeeping by physicians.** The previous example illustrates the role of CT personnel in determining who is offered a trial. This process, called gatekeeping, refers to the process whereby CT personnel determine which patients they will approach about a trial. CT
personnel remarked on the nature of gatekeeping by physicians and how not offering a trial to a particular patient immediately forecloses the accrual of that patient into a trial. From the interviews, it became apparent that gatekeeping involved pre-screening patients for trial eligibility and was a strategy some physicians used prior to initiating a trial discussion in order to save time and resources. Thus, CT personnel recognized the structural component to patients’ relational autonomy, where oncologists decide who receives a CT offer, and that this decision is influenced by limited CT and healthcare resources. As one radiation oncologist shared:

So even if I’m not thinking about the patient in front of me, I’m thinking, okay, is it a worthwhile investment of the extra time to offer this trial to this patient and in those sorts of cases, it isn’t, right. So I can move on with my day much more quickly if I pre-filter.

CT personnel talked about two kinds of screening practices based on trial protocol eligibility criteria: patient pathology and social factors. CT personnel perceived the assessment of pathology as relatively straightforward; however, assessing patients’ social situation was viewed as more challenging. As one oncologist described:

So we can break it down into the patient characteristics and the pathology. So one is, do they actually meet the eligibility? So do they have the right pathology -The eligibility criteria? And that’s the easy part because that’s just a simple checklist. The next is probably the harder intangible stuff. Is this a person who really understands what a clinical trial is? Is this a person who truly is suitable for someone who – and it depends on each trial. Some trials have much more rigorous tests. Some are quite easy and simplistic in terms of the logistics. So not every trial will suit every patient.

Cancer patients’ mental competency was seen by CT personnel as having an important role to play in the suitability of patients for CTs and in physicians’ determinations of whether or not to offer a trial to a particular patient. As one CT nurse remarked:

Yeah, they don’t have any major mental health issues that would be troublesome while in a clinical trial or questioned, because there’s always that part of the
eligibility that they have to have, like, certain mental competence to be eligible for the trial.

Another oncologist commented on how, in his mind, the criterion of mental competency for CT participation outright excludes certain patient populations with psychiatric disorders or addictions:

Definitely the ones who, you know, drug addiction or the downtown east side population\textsuperscript{12} are not patients who I put on trials. And patients with depression or psychiatric disorders I tend not to, either, (a) because of the medications and (b) they’re just – you don’t know whether they really truly understand the trial and it can get very complicated.

CT personnel recognized that the sort of person who is a good fit for a trial is an “exceptional person”, someone who is competent and able to think clearly about the trial. These characteristics mimic the ideal autonomous person, or someone with all the resources of the upper echelon of society. However, acknowledging the relational aspects of autonomy, CT personnel also believed it was desirable to have patients who have family nearby to provide social support during the patient’s CT participation. As one oncologist elaborated:

Living with someone who supports – so, ideally, a married couple is always a good thing because you know a spouse is normally there for support. And that’s not to say single people shouldn’t go on trials. Well supported single people – and even if they don’t have families but have a very supportive friend network, you know, these are people who normally come with a friend. They might be taking notes. Where I tend to be a bit more worried is sort of the person who lives on their own, doesn’t seem to have a lot of friends, may have a lot of pets. Those are the ones you tend to worry a bit more.

**Family member influence.** Relational influences were most clearly seen when CT personnel spoke about the influence of family and friends on patients’ CT decisions. In

\textsuperscript{12}The downtown east side (DTES) is considered one of the poorest areas in Canada. It has a very high incidence of drug use, poverty, crime, violence and sex trade (Brethour 2009).
addition to physicians, family members or close friends were also perceived to influence patients’ decisions to participate in CTs. As one participant remarked, “some people go into studies to please the doctor or to please their spouse or…that framework and a sense of doing what is right for others.” Sometimes the influence was seen as being a quiet nudge in the direction of a trial or a suggestion to look into a trial that the family member heard about in the media or online. Other times a friend or a neighbour of the family might have had a good experience with being involved in CTs. Advice from family or trusted others was seen as opening patients to the possibility of participating in a trial even before the oncologist presents CTs as an option. One CT nurse reflected upon the role of trusting relationships with family members and how this impacts patients’ CT decision making:

They’ve had family members say, ‘hey, when you go, ask, because this is good stuff. I’m reading all this good stuff about this particular trial. They’re doing this trial, ask if you can be on this trial.’ So they would already be coming in then with an open mind and wanting to be a participant if they can because they’ve already been convinced by someone they trust in the family to already ask about it.

On the flipside, CT personnel thought that if a family member has had a negative experience with trial participation, cancer treatment or cancer care, this could influence patients’ decision making by limiting patients’ willingness to hear more about CTs. As one CT nurse explained:

Some people who are convinced that they don’t want to do trials, you can almost see it when you’re talking to them. They have already made up their mind. They’re closed to that option so they’re not really, they’re open to hearing about anything that might be there in the first place and those people might have had other experiences happen in their lives or with other family members being on stuff… If that family member had a grandpa that died horribly after being radiated or had chemo and had horrible side effects or whatever, in their head, chemo is horrible.

At times, the support or encouragement related to participating in CTs provided by a family member or a significant other was seen to move well beyond a simple suggestion.
Instead, some CT personnel spoke about patients being “pressured” by trusted others to enter into a trial. This was perceived to be problematic because, as one radiation oncologist shared, “you’ll see people do it because their family really wants them to, so it isn’t even for their own reasons. It’ll be because other people are telling them they should.” CT personnel particularly noted that spouses of prostate cancer patients tended to be intimately involved in patients’ decision making about CTs and sometimes were perceived to outright influence patients’ decisions. As an oncologist described:

I think certainly for the men in prostate cancer, their wives and family and caregivers, the primary caregiver, has a huge impact on that decision. More often than not—this is my bias—the wives tend to push the husbands into doing clinical trials and kind of actually help make that decision for them. More often than not, they actually do push I think for the patient to go on a study.

When asked why family members were motivated to encourage or push patients to participate in trials, CT personnel believed it is because families value their relationship with their loved one and were looking out for the patient’s best interests. Other times, family members were perceived to be influenced by their own personal fears associated with losing a loved one to cancer. One radiation oncologist mused how some loved ones may also be overcompensating for the guilt they feel for not living close to the patient:

And a lot of it can be tied into their own belief system and also their own fear that they’re going to lose their relative, tied up in the fact that they don’t live there and they feel guilty and they wish they could be there. There’s all kinds of personal issues for them and they really have nothing to do, if anything, with what’s good for the patient or him or herself.

Some CT personnel believed patients might make CT decisions that place the needs of the family before their own because they wanted to avoid further upsetting their loved ones. As one oncologist shared:

I think sometimes some patients are worried about being a burden to their family. The other aspect of it, some patients are afraid to decline a trial because then they feel like
they’re not doing everything and their family is going to get upset with them as well. So it’s not so much that we’re [CT personnel] coercive but that the family is coercive.

When asked specifically what being a ‘burden’ to one’s family meant, another oncologist perceived it differently and described burden as being patients’ worry about imposing upon their family to attend CTs and related activities:

Some patients say, ‘Well, I don’t have a ride to come in. I feel like I’m burdening my family with all these extra tests and coming in. I’m going to experience more side effects.’ I think sometimes some patients are worried about being a burden to their family.

Other cancer patients were perceived to decline CT participation because of the time commitment and how it might interfere with their daily lives or family responsibilities. As one CT nurse mentioned, patients can be very protective of their family time:

And then the other force is of course the family. Like, you know if they have little kids. Those doors will be first and you would be silly, you will not have a patient if you tell them that you can’t accommodate for their immediate family issues. And if you cannot accommodate, then you can’t do it.

In contrast, CT personnel explained that some patients considered participating in a trial because of the responsibility they felt towards caring for their family or young children. An oncologist recounted an experience with a young woman with advanced cancer who wanted to go on a trial in order to have a future with her children:

She came over because her oncologist had given her two cycles of chemo, she’s a young woman, she’s got three young kids and he said he had nothing else to offer her and ... But she could come over and talk to me about experimental therapy. So she came over in the hope that there would be other treatment options for her and she said – I’ve got three young kids, I’m a mother, I want to do everything I can with this.

**Structural Influences on Patients’ Decision-making**

In addition to personal and social reasons, CT personnel also identified structural factors that they perceived to influence cancer patients’ CT decision making. For example,
CT personnel believed many cancer patients participated in trials because they correctly perceived them as a gateway to better treatment and specialized care.

Access to drugs. CT personnel described situations where patients accepted CT participation because it was the only way to gain access to new treatments or promising drugs that were not yet approved for standard care or available as part of the cancer agency’s formulary. CT personnel also described patients as entering a CT in order to receive a drug earlier than they would have otherwise been eligible for given their disease stage. These patients saw CT participation as being a “loop hole” in the system because it allowed them to bypass the wait until they were eligible to receive the drug as part of their standard care. As one CT nurse shared:

Say there’s a new drug...I’m not sure if you’re familiar with the Phase I, II and III part of it. So after Phase I, sometimes we do the phase two studies; so those drugs, patients can get access to. So it can be a new targeted therapy drug that, technically, won’t be covered if someone, let’s say, is only at stage I cancer and they’re getting their first line of treatment. This drug can only...say, this new study drug or another drug is only...they can only access it on the third line of treatment. They can actually access it earlier in the study.

CT personnel also believed hospital or provincial-level policy making about oncology drug coverage impacts patients’ CT decision making. Patients were perceived to consider the cost-savings of accessing a promising drug through a CT instead of paying for it out of pocket. As one CT nurse explains:

Well, like, if they’re in a clinical trial, they don’t pay for any drug but, if they were off the clinical trial and if it was a drug that was on the market, sometimes they’re not through the systemic therapy program. The clinicians that are involved with the systemic therapy program, they decide every year which drugs are going to be covered by MSP and which are not, right? So there are some drugs out there that people go elsewhere and purchase and have in I.V. infusions off site but they’re paying for those drugs themselves. So, if they’re in a clinical trial, they don’t pay for any drugs, they’re all paid for. They’re free.
Access to care benefits. In addition to drug access, some cancer patients were perceived to want to participate in CTs because they believed the extra clinic visits, blood work and tests would lead to better care. One CT nurse shared her belief that patients appreciated the more intensive follow-up if they participated in CTs:

They feel confident that someone is looking at their results of their scans and their blood work and somebody’s on it, somebody is following it closer than if they weren’t on a clinical trial.

Many CT personnel also believed patients would receive access to “preferential treatment” within a trial. As one participant stated, “I think there’s a correct perception that if you’re in a trial, your care is better.” When asked where patients might get this perception, a radiation oncologist explained it might come from the consent form:

It’s often implied actually within consent forms that the follow-up care will be more in a randomized trial than it would be for routine care. I’m not quite sure that I’m happy about that as a statement but it’s certainly at least implied in all the consent forms I’ve seen.

Patients who participated in CTs were perceived to receive additional nursing support, including a singular trial nurse that organized their appointments and addressed their questions and concerns. This additional support was seen to improve patients’ continuity of care and helped them navigate an otherwise increasingly fragmented cancer care system. Sometimes this added benefit was not fully appreciated until patients came off a trial or withdraw from a trial, as one CT nurse explained:

But I think that generally when patients are not on clinical trials, they do realize the care, the attentiveness that they had for one person organizing their appointments and one person to contact when they had problems is kind of value versus them calling different numbers for different problems.

In general, CT personnel believed CTs addressed a structural gap in care and were better able to support vulnerable patients than standard care. One oncologist reflected on how
the current cancer care system does not provide the care and attention all patients required in the standard treatment setting. This makes the option of a CT and all the associated care benefits considerably more appealing to most patients:

And I think there’s perhaps a little bit more of that now than there used to be because the cancer care system has been hacked to bits and you know, people who aren’t on clinical trials don’t tend to get the TLC perhaps that they used to.

Complexity of trials. Some CT personnel identified trial complexity as a barrier to centres being able to host CTs because there were insufficient resources to support and coordinate complex CT procedures. As one CT nurse explained:

But do they want to do it or is it a really cumbersome trial, or is it – or we can’t make it work in our building, i.e. that we can’t, if they need three CT scans or something a week, well we can’t do that here because there’s such a wait list for CT scans for example.

As a consequence, patients located in these centres were denied the opportunity to participate in such CTs. Instead, complex CTs were typically offered in urban hospitals or cancer centres that have more resources for their execution. However, CT personnel believed the predominance of trials within urban cancer centres made CTs less accessible to rural patients. Patients who live far away are required to pay more out of pocket to attend a trial because compensation for travelling to the study site is not supported by CT funds, especially if it is a collaborative oncology trial as opposed to a pharmaceutical drug trial. As one CT nurse elaborated:

There’s not a lot of pockets of money for people to come to [city] to participate in a clinical trial. We do occasionally pay travel expenses but it’s not total reimbursement, it’s usually a partial pay. And that would only be trials that are drug company trials, run by pharmaceutical companies. The Cooperative Group trials through, like, National Cancer Institute of Canada, there’s usually no payment other than we can occasionally pay for parking.
Complex versus simple trial protocol design was also seen to influence patients’ ability to understand what CTs involve since the presence of randomization was perceived to make a trial more complex and difficult for patients to understand. Complex protocols also influenced physician’s gatekeeping decisions about which patients should be offered the option of CTs based on their assumptions about patients’ competency and ability to grasp randomization. One oncologist believed studies will only increase in complexity as cancer care itself is getting more complicated; he perceived this clinical reality as a structural barrier to patients’ CT decision making:

I think the nature of some of the trials we’re doing are just so complex now. Even in our site, we’ve got a couple of these British trials where they have multiple randomization and sub randomizations. I mean, one randomization that people get, what…what do you mean a randomization? But then when you get into multiple randomizations and they can choose arms and all this kind of stuff. That’s confusing, that’s a hindrance. And then if the modalities that are being studied are complicated, people just…I mean, cancer care is getting more complicated. And it’s not just the treatment they’re studying but also the extra tests required. There’s a lot more translational sub-studies and stuff, and people go, oh, my God…so it’s overwhelming. That’s a hindrance. So they’re already loaded with multi-modality treatment programs and multiple appointments and stuff, and the fact that the system around them has become much less well resourced.

Consent forms were also seen as particularly problematic. Despite the research ethics requirement that forms should be written in lay language and typically at a grade six reading level, CT personnel perceived them to be too detailed, which made concepts such as randomization difficult to understand. As one CT nurse stated, even basic information about CTs is difficult for patients to assimilate:

There’s stuff in the consent that the patient may not be able to put into terms of a real life context in terms of the amount of time that’s going to be required for their participation and what the visits might look like, what the tests for the workup are while they’re on study and making sense of a long list of side effects.
Oncologists believed too much information in consent forms was actually a hindrance to patients’ autonomy and caused some patients to feel “paralyz[ed]”, where they felt unable to make a good decision. As explained by one oncologist:

You know anything happening to a person, you get into what’s going to be done with their tissue or whatever and then you get into where the documents go and who has access. It [the consent form] just goes on and on and on and somehow that doesn’t, I think, work. Somehow I think that makes people less autonomous in terms of decisions because I think you’re over informing them and initially at least, confusing them.

Difficulties with understanding information provided in the consent form was perceived to be more apparent among non-English speaking patients who often relied on family members to interpret complex trial information. This underscores the need for CT specific translation services or education for non-English speaking populations:

I cannot judge what the interpreter has interpreted to that person and you know usually if there’s a family member, then you want the family there also because it’s just better to have more, but yeah. And that’s becoming a bigger issue with more and more of the studies and the more complex, the harder it is on the interpreter and the interpreting of the information.

Finally, the timing of when to provide CT information was also seen to be important for patients’ understanding. For patients who were newly diagnosed, CT personnel perceived these individuals as not being ready to learn about CTs. Instead, as one radiation oncologist described, these patients are focused on their prognosis and standard treatment options:

So to then give them additional information about a study, which in the big scheme of things is much less important than things like, am I going to live or die, what treatment am I going to have, what are the side effects, which are really the key things the patient needs to know, so it’s probably not the ideal time to talk about a trial.

When CT personnel did discuss trial information with patients, one of their main concerns was about having sufficient infrastructure to support their discussion. Sufficient time needed to be built into clinic hours to provide information and decisional support to
patients, especially when patients were very anxious and needed a lot of support. As shared by one CT nurse:

A lot of people are very anxious when this is going on, especially if it’s – they feel that they’ve got disease, they want it treated and that and so you can talk to them and kind of explain something to them and you can’t explain, even though they read it, you can’t explain every detail of it in 15 minutes, you know when time is a huge factor.

Even though CT personnel tried to give patients enough time and space to digest the information and explore both experimental and standard options, CT personnel sometimes experienced pressure to obtain informed consent quickly due to pre-defined windows of eligibility to enroll patients into trials. As one CT nurse stated; “there’s a bit of a time crunch for getting patients on a clinical trial.” If too many weeks or months pass, patients may not still be eligible for the CT. Other times, trials may be dependent upon, for example, receiving tests within a specified window. As one CT nurse commented, this can create a “high pressure” situation to obtain consent within a matter of days:

For the ones [CTs] with the shorter turnaround, then I need to know much sooner than that. So usually they’ve been seen on a Wednesday or a Friday, Tuesday, Wednesday or a Friday. If they’re seen on a Tuesday, I’ll call them on a Friday. If they’re seen on a Friday, I’ll be calling them on Monday, kind of thing, to know, okay, do you want to do this? All right. Now you need to come in. This is what you need to do. Because often when they’re quick turnaround, we need them to sign consent before we can send tissue, it’s, like, nothing starts until you sign that consent. So you need to come in, you need to think about it, you need to work on that. So there’s high pressure if there’s fast turnaround.

**Recommendations**

Interviews with CT personnel explored best practices for supporting patients’ relational autonomy in their decision making about CT participation. The recommendations discussed below include suggestions from CT personnel about ways patients can be personally, socially and structurally supported in their CT decision making.
**Provision of Clinical Trial Decision-making Support**

CT personnel spoke about the need to provide “individualized” support to patients when they are faced with making decisions about CT participation. This could include tailored support for synthesizing information, psychological support for decision making and promoting patients’ sense of control and autonomy over the decision. CT personnel believed support from the healthcare team was especially important when families were not willing or available to take on a supportive role. One medical oncologist described his strategy for supporting patients:

> And I think I spend a lot of time talking to my patients about the study and what it means and the benefits and the risks. And I think they appreciate that […] I actually sit down and I go through the whole consent and study and the pros and cons as well of going on a study *versus* not going on a study. And I make myself available for any call that they want.

Other CT personnel explained the necessity of alleviating the fear or burden of making a wrong decision through the provision of information. This was an important part of supporting patients’ relational autonomy and CT decision making. As one medical oncologist explained:

> I find if you give them more information and relieve them of the burden of making a wrong decision, that any decision they make is the right decision for them. More often than not, that actually helps for them to decide to do a trial in fact, once they have that belief taken away from them.

CT personnel also described how they might offer reassurance to patients by reminding them that they can always withdraw from the CT and that “they will still get good care even if they’re not in a clinical trial.” This gives patients a feeling of control, and relieves their anxiety, as described by one CT nurse:

> So those people who can’t make up their minds, to help with their autonomous decision is reassurance and often, the only way that I reassure people is by saying, and the doctor says this too, at any point in time you can get off the trial. So here’s
what we think, here’s what we believe, anytime, you don’t like the drugs, even if the drugs are not affecting you. You just don’t like being here, whatever, you don’t like all the appointments, the way they’re set up, you can leave. Any time at all you can leave and that helps people a lot to feel like that they are making a decision that they have a bit of control.

**Mobilization of Social Resources**

CT personnel recognized that it is often necessary to provide culturally sensitive decision-making support for patients. One radiation oncologist emphasized the importance of appreciating the patients’ perspective and then mobilizing resources from the patients’ cultural community in order to facilitate their decision making:

So for some patients who need the interaction with their culture, with cultural caregivers or community in order to derive a decision, I mean my job is to facilitate that. I mean I’ve got to help people come to a decision using whatever resources they have, not whatever resources I have, whatever resources they have.

One of the key recommendations from CT personnel was to recognize how important family and community are for supporting cancer patients’ relational autonomy and decision making about CTs. One CT nurse remarked “they’re [patients] more able to be autonomous if they have good family bonds and good social backup, good connections out there.” She explained the role of social connections in the following way:

I think they help them to function. They might be supportive in other ways, you know, they might provide some kind of a service to them so I think, if patients are socially connected, then they’ll have a GP. They’ll also have possibly some home care coming in or some kind of assistance. And, if they have family, then I think the family members can help to support them emotionally but also financially sometimes. Some of these patients are actually living with family members so finances are a big problem when you’re ill, especially with cancer because, you know, people sometimes have to go on disability. Sometimes they have to retire early or sometimes they’re even let go or their business falls apart if they’re self-employed, they have their own company. So family can help out in financial dire straits, too.
**Attention to Structural Barriers**

CT personnel considered overall system issues and how CT infrastructure could be re-developed to support patients’ assimilation and appreciation of CT information. One radiation oncologist suggested a triage system whereby patients who were eligible for a CT were followed up separately in a clinic that allowed for more time to discuss the trial:

I think it’s the whole sort of lack of infrastructure and timing, time issue. If we had, if we knew up front who was definitely not eligible for a study and who might be eligible for a study, then you could conceive of a system whereby, instead of having one clinic, say as a follow-up clinic, and patients scheduled every fifteen minutes, or every ten minutes or whatever it is, you could have like a clinic where people are scheduled every twenty minutes, and there’d be other clinics where there’s no question of a trial every five minutes you know, so that you could create more time.

Reflecting on structural influences, and how to better support patients’ relational autonomy in trial decisions, particularly CTs that require a quick turnaround, one CT nurse expressed some exasperation about how to allow more time for patients to digest CT information. This nurse decided that it might come down to re-designing trials to make them more patient-friendly:

I think that if we can give them as much time as possible, to not pressure them. But I don’t know how to fix that, because with some trials you can and when they have the time, they are given the time, and with others you can’t because that is just the way the trial is built. So if you want to help with that, then you have to go back even further and say, don’t write trials that are like this.

Many CT personnel believed communication resources to support the provision of trial information in a patient’s own language was also important for patients’ relational autonomy and decision making about CTs. This suggestion could apply to all trial offers, not just cancer CTs. For example, when patients are not English speaking, having a doctor or a family member “who speaks their language, can read the English and then talk to them about
"it" was seen as helpful. This may be particularly important for consent forms and other trial material, as suggested by a CT nurse:

> We could try to provide them with consents in their own language. Questions in their own language. We try that now. We do. We ask, because lots of clinical trials have lots of quality of life questionnaires and they are supposed to be only done by the patient, not even a family member. And so it’s hard to do if you do not speak the language or read the language. And it’s hard to understand. And now most of our population, we have a huge population that doesn’t speak the language. And so we should really, to make it easier for them, we should provide them with information that they can communicate in.

**Summary of Findings**

The present discussion has identified several overarching themes within the CT personnel findings that involve personal, social, and structural influences on cancer patients’ relational autonomy and CT decision making. In this summary, these themes are explored in greater detail in the context of the findings. In Chapter Six, these themes will be more broadly situated in relation to the current literature and theoretical lens of relational autonomy.

In examining the personal, social, and structural factors in CT decision-making, three major themes are apparent from interviews with CT personnel. First, there is an apparent power differential between patients and oncologists that may place undue pressure on patients’ trial decision-making. Patients are dependent on oncologists for their continued care, which creates a strong incentive for them to make trial decisions that do not jeopardize their relationship. Second, findings demonstrate the pervasiveness of the therapeutic misconception in trial discussions, both for patients and CT personnel. Oncologists may present and discuss CTs in a way that makes it difficult for patients to distinguish a CT from usual/standard care. This may be intentional or inadvertent, as oncologists may also be confused about the distinction. Linked to this is the concern that patients do not understand
the nuances of what is presented to them, often because of their anxiety or fear, and lack the ability to provide truly informed consent to trial participation. Third, justice issues arise in relation to selective gatekeeping by oncologists and equitable access to CTs across different socioeconomic, geographic and demographic groups. Such practices and barriers have implications for appropriate randomization and fair access to CTs especially for populations marginalized by factors such as geography, poverty, immigration status and language. The following sections elaborate on these themes in greater detail and touch on the ways in which personal, social, and structural influences are all intricately involved and overlapping in these issues.

**Power Differences Between Patients and Physicians**

Findings indicate that patients with cancer are vulnerable to many strong emotions throughout their cancer trajectory. CT personnel identified hope, fear, anxiety and distress as especially prevalent emotions that a majority of patients experience in response to their cancer diagnosis. These emotions make it difficult for patients to appreciate CT information, and many cancer patients are thus dependent upon CT personnel for support to understand and undergo care. For example, CT personnel interviews revealed that cancer patients often experience psychological distress and anxiety as a result of receiving their cancer diagnosis, which places them at a disadvantage when it comes to feeling capable of receiving information and empowered to make decisions. In addition, patients often struggle to comprehend their diagnosis, prognosis and treatment options because of their unfamiliarity with the cancer care system. This creates unease and uncertainty for patients when they approach consultations with their oncology healthcare provider. Finally, CT personnel have
recommended that patients need substantial social (i.e., provider as well as family) support to assist them with the logistics of CT participation.

For all these reasons, cancer patients are heavily reliant on CT personnel, especially their oncologists. These physicians hold medical knowledge that patients require to make treatment or trial choices but that they themselves lack. Patients’ attempts to seek medical information such as their risk of cancer recurrence/growth if they participated (or not) in a trial from CT nurses were unsuccessful because of their restricted scop of practice. Patients were instead referred back to their oncologist to have more nuanced medical discussions. This reinforced a power imbalance where patients are dependent upon physicians. It would come as no surprise then that patients would make trial decisions to maintain good relationships with their oncologists so that they may continue to receive care and assistance. Furthermore, if patients are under emotional distress they may not want to engender conflicted relationships that may add to their distress. This is played out in the findings with CT personnel where it was discussed that some patients accept trial participation out of a desire to please their oncologist or out of a duty to give thanks for the care they have received. Other patients are reported to make CT decisions out of the fear that they will suffer consequences to their care if they do not participate. These findings attest to the significant influence oncologists have on patients’ relational autonomy and CT decision making, and raise concern that patients may feel pressured to make trial decisions to preserve relationships with their oncologists.

**Therapeutic Misconception**

Another important issue identified from interviews with CT personnel is the perceived dual role of the treating physician who is also the physician-researcher. This has
the consequence of encouraging patients’ therapeutic misconception of trials, which is
defined as the mistaken belief that the purpose of CTs is to provide individualized care rather
than further scientific understanding (Appelbaum, Roth, & Lidz 1982). When oncologists
introduce the concept of a trial in the clinic, the patient is already conditioned to engage in a
discussion about treatment rather than CTs. There is also the perception that oncologists may
downplay the experimental nature of trials and the associated risks and sometimes use the
terms “trial” and “treatment” interchangeably in accrual discussions.

Many CT personnel, however, perceived oncologists to have the best of intentions in
blurring the line between treatments and CTs. They may perceive a trial as the only way to
access a treatment option for their patients and may downplay the experimental nature of CTs
if they are also aware of patients’ hesitancy to participate because of their fears and beliefs
about trial participation. However, presenting trials in this manner may mislead patients into
believing that the trial intervention is known to be efficacious when, in fact, there is still
medical uncertainty about its effectiveness and risk profile. Even if recruiting physicians
genuinely believe the trial offers the most effective therapy for their patient, if other members
of the expert community disagree they are obligated to disclose this to their patients. This
moral requirement is rooted in clinical equipoise, which Canadian research ethics guidelines
stipulate must be present in order for trials to be carried out ethically (CIHR 2010). Clinical
equipoise is obtained when there is genuine uncertainty in the medical community over
which arm of a trial is superior. Once it is established with certainty that one arm is more
beneficial, all patients are entitled to receive the superior treatment (Freedman 1987).

Structural issues exacerbate the therapeutic misconception and impact patients’
understanding necessary for CT decision making and informed consent. For example, the
cancer care system and CT appointments are not structured in such a way that oncologists, who are often involved in recruiting to their own studies, are able to discuss trials separate from treatment. Therefore, oncologists have no choice but to discuss trials alongside treatment and within a limited time slot that makes having a more thorough discussion with patients difficult. Language or literacy barriers may place further challenges on the trial discussion and on patients’ ability to understand the information imparted to them. In terms of providing unbiased information for patients’ informed consent, findings suggest there are professional and institutional pressures for oncologists to recruit for or champion trials that are running at the agency or in their department. This may influence the trial discussion and encourage patients’ therapeutic misconception even if the physician presenting the trial is not directly involved or is careful to remain neutral in his or her discussion with patients. As the findings indicate, subtle clues and biases are difficult for providers to identify and control. Oncologists’ body language, amount of time they allot to discussing trials, and how they phrase the CT discussion may reveal information to patients about how they feel about a trial, suggesting the need for professionals to ensure that these pressures do not unduly influence the trial discussion and encourage the therapeutic misconception in patients’ CT decision making.

**Equitable Access to Clinical Trials**

Finally, findings indicate that not all cancer patients are equally able to access CTs. Strict trial eligibility requirements, pre-screening or gatekeeping behavior by oncologists, and lack of trial resources are social and structural influences that are perceived to affect cancer patients’ access to trials. Because of insufficient resources directed towards CT accrual activities, oncologists are forced to pre-screen patients for recruitment into trials. Persons
with mental health issues and addictions are often selectively denied access to CTs because they are perceived to not have the up-front capacity to understand the trial and therefore require more resources to support their understanding of and participation in CTs. Lack of family or other social support and poverty can also negatively impact patients’ ability to access CTs due to the assumptions oncologists develop about these patients’ ability to participate in CTs. Also, interviews suggest rural cancer patients are approached less often to participate in CTs because of assumptions made about their financial means and the lack of funding to cover the cost of travel to the study site.

However, the resultant pre-screening practices by oncologists may be based upon erroneous assumptions about the capacity of certain groups to take part.\textsuperscript{13} The result is that already marginalized groups, those who have mental health issues or addictions and those who have lower socioeconomic status or who live in rural areas, will unfairly have decreased or no access to CTs. This impacts not only the ability of these persons to access potentially helpful interventions but it also compromises the scientific integrity of CTs since interventions would not be appropriately randomized across all patient groups. Thus, in an era of evidence-based medicine where the synthesis of the best available randomized controlled trials inform practice and policy decisions, the generalizability of study findings may be limited, which may result in unknown risks and benefits to these populations (Rogers 2004).

\textsuperscript{13} Pre-screening practices are also a result of systemic barriers to oncologists’ time to discuss trials with patients.
Chapter Five: "No Wo/Man is an Island"—Cancer Patients' Experience of Autonomy Related to Their Decision-Making Process about Clinical Trial Participation

This chapter presents the results from the grounded theory study of cancer patients’ decision-making process and explains how patients made decisions about clinical trials (CTs). Support persons and CT personnel perspectives were used to provide further insight into patients’ decision-making process and relational autonomy. The overall aim of the study was to develop a theoretical model that illustrates patients’ decision-making process in order to provide a foundation for the development of decision support strategies that will enhance cancer patients’ relational autonomy and inform how they are approached, recruited, and enrolled in cancer CTs.

A total of 24 breast, 15 prostate, and 1 bladder adult cancer patients who had accepted (n=32), declined (n=6), or withdrawn (n=2) from a CT participated in this study. Most of the CTs discussed by patients were phase II or III pharmaceutical trials (n=37). The majority of participants were between 50-70 years old (n=23), were Caucasian (n=35), and were married or common law (n=29). Almost all the participants (n=34) had a college/trade or university degree, including graduate degree. Patients were representative of a range of disease stages. Some had advanced disease (n=16), others had intermediate disease (n=10), and the rest had early stage of disease (n=13). Additional demographic characteristics of the patient participants can be found in Table 5.1.

14 The percentage of acceptors, decliners, and withdrawers from CTs reported here are reflective of patients’ current or most recent CT decisions. However, during the interviews, some patients reflected upon their previous CT experience, in which they made different decisions. Every effort was made in the reporting of patient quotes to cite the relevant CT decision (past or most recent decision).
Table 5.1 – Reported Patient Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Frequency (%)</th>
<th>Characteristic</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td><strong>Self-Reported Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>&lt;40 years</td>
<td>1 (2.5%)</td>
<td>Caucasian</td>
<td>35 (87.5%)</td>
</tr>
<tr>
<td>41-50 years</td>
<td>6 (15.0%)</td>
<td>Asian</td>
<td>2 (5.0%)</td>
</tr>
<tr>
<td>51-60 years</td>
<td>11 (27.5%)</td>
<td>Aboriginal</td>
<td>1 (2.5%)</td>
</tr>
<tr>
<td>61-70 years</td>
<td>12 (30.0%)</td>
<td>African Canadian</td>
<td>1 (2.5%)</td>
</tr>
<tr>
<td>&gt;70 years</td>
<td>7 (17.5%)</td>
<td>Unknown</td>
<td>1 (2.5%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>3 (7.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td><strong>Type of Cancer</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>15 (37.5%)</td>
<td>Breast</td>
<td>24 (60.0%)</td>
</tr>
<tr>
<td>Female</td>
<td>25 (62.5%)</td>
<td>Prostate</td>
<td>15 (37.5%)</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td><strong>Stage of Cancer</strong></td>
<td></td>
</tr>
<tr>
<td>Married/common-law</td>
<td>29 (72.5%)</td>
<td>Early</td>
<td>13 (32.5%)</td>
</tr>
<tr>
<td>Divorced/ widowed/ single</td>
<td>10 (25.0%)</td>
<td>Intermediate</td>
<td>10 (25.0%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>1 (2.5%)</td>
<td>Advanced</td>
<td>16 (40.0%)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td><strong>Trial Decision</strong></td>
<td></td>
</tr>
<tr>
<td>High school diploma</td>
<td>5 (12.5%)</td>
<td>Unknown</td>
<td>1 (2.5%)</td>
</tr>
<tr>
<td>College/trade school</td>
<td>7 (17.5%)</td>
<td>Accepted</td>
<td>32 (80.0%)</td>
</tr>
<tr>
<td>University</td>
<td>13 (32.5%)</td>
<td>Declined</td>
<td>6 (15.0%)</td>
</tr>
<tr>
<td>Graduate or professional degree</td>
<td>14 (35.0%)</td>
<td>Withdrawn</td>
<td>2 (5.0%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>1 (2.5%)</td>
<td></td>
<td></td>
</tr>
</tbody>
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**Introduction to the Theory**

The following paragraphs provide an overview of the theory describing cancer patients’ decision-making process related to CT participation. The theory identifies key phases, processes, and sub-processes of patients’ decision making. More fulsome explanations, along with supportive participant quotes, will be used in the body of this chapter to elaborate on the theory and central core construct “No Wo/Man is an Island”.

**No Wo/Man is an Island**

“No wo/man is an island” was the central core construct describing breast and prostate cancer patients’ CT decision-making process. This construct captured the relational complexity of cancer patients’ CT decision-making and made visible the various key influences on this process. In particular, significant relationships, including relationships with
partners, family and extended family or friends, as well as the broader social and structural
environment influenced patients’ CT decision making. A patient explained:

…no person can do everything by themselves - you know, no man is an island. But
anyway, I took advice from many people and they pretty well all had the same idea
[to accept CT participation] (male, accepted).

A CT nurse who participated in the study described how social support (e.g.,
supportive family, friends, and physicians) intertwined with structural support (e.g.,
accessible healthcare, economic resources) to create a relational system that facilitated cancer
patients’ decision-making process about CTs:

I think they [family bonds and social connections] help them [patients] to function.
They might be supportive in other ways, you know, they might provide some kind of
a service to them. So I think, if patients are socially connected, then they’ll have a GP
[general practitioner]. They’ll also have possibly some home care coming in or some
kind of assistance. And, if they have family, then I think the family members can help
to support them emotionally but also financially sometimes.

Three general phases\(^\text{15}\) made up the “No Wo/Man is an Island” theoretical model
(see Figure 5.1). Consistent with the core concept, a relational component was imbedded
throughout all phases, processes and sub-processes. This reflected not only how relationships
influenced how patients moved through the phases in the model but also encompassed the
larger socio-political influences (e.g., availability of resources, geographical location)
embedded in the theoretical model.

The first phase occurred prior to the trial offer and related to the influence of
predisposing factors on patients’ level of receptivity to receiving CT information from their
physicians. In this phase, social and cultural norms around cancer CTs, along with familial

\(^{15}\text{Bolded or italicized text in this chapter highlights major themes and processes that were identified during data analysis.}\)
experience were key influences on patients’ beliefs and attitudes. For example, personal and cultural understandings of research and medical technology, family and support networks’ opinions, previous CT / healthcare experiences, and social media were highly influential. These factors then interacted with one another and affected how “open” or “closed” patients were to learning about CTs.  

The second phase of the model was the trial offer phase, which referred to the physician’s initial presentation of the CT to the patient. Within this phase, physicians’ framing of the trial and their non-verbal cues proved to be important for patients’ initial assessment of the trial and was helpful for them in gleaning their physician’s opinion of the trial. Whether a trial was even offered as an option at this point was an important structural precondition for patients’ further engagement in the “No Wo/Man is an Island” model. This phase highlights the important role of the patient-oncologist relationship related to patients’ decision-making process and the socio-political context in which these relationships were imbedded.

The third phase was composed of patients’ CT decision making within which there were three processes: seeking information, establishing credibility, and weighing pros and cons. The weighing pros and cons process further consisted of several sub-processes. These included doing what is right for me/considering altruism, weighing adverse effects/benefits, grappling with uncertainty, considering logistics and maintaining relationships. Depending upon whether the type of decision making was snap or reflective, patients had more or less

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16 How “open” or “closed” patients were refers to how receptive patients, who received a trial offer, were to hearing about CT information. As such, these concepts/themes do not apply to patients who were not offered a trial due to gatekeeping behaviours by physicians.
engagement in these sub-processes. Snap decision-makers tended to seek minimal information and established the credibility only of their physician or care team before making a decision about whether or not to participate in a CT. These decision-makers bypassed or only minimally engaged in weighing pros and cons and related sub-processes. In contrast, reflective decision-makers engaged in all processes and sub-processes. Within this phase, larger social norms and expectations around cancer CTs, socio-political barriers and facilitators of patients’ CT decision-making, and the role of social networks were important influences in guiding patients through these processes.

Finally, a broad range of influential factors informed the decision-making phase of the model. These factors included patients’ stage of disease, trial type (whether it was an exercise or a drug trial), previous and current healthcare experience, and gender. These factors influenced what kinds of and how much information was important to patients, to what extent trust and credibility was significant, and how patients weighed the pros and cons of CT participation. Additionally, stage of disease and trial type influenced patients’ weighing of pros and cons through the mediating concepts of risk tolerance and choice perception. Patients who reported more advanced stage of disease, for example, demonstrated greater tolerance for uncertainty associated with the trial (i.e., whether or not they would receive the active agent, whether or not the agent would be effective for them) and minimized the risk of adverse effects because they perceived no other treatment options available.

At the end of the three, mostly sequential phases, patients ultimately reached a decision to either accept or decline trial participation. However, some participants who originally accepted returned to the decision-making phase, reconsidered their decision, and
withdrew from the trial. The overall theory highlights how CT decision making is not only personally but also socially and structurally located and demonstrates key phases and processes that patients go through in order to make a CT decision. In the following sections a more in-depth description is provided and supported by quotes from participants.
Figure 5.1 - "No Wo/Man is an Island"
Phase I: Prior to the Clinical Trial Offer - Predisposing Factors

Prior to being offered a trial by their physician, predisposing factors such as patients’ pre-conceived beliefs and attitudes about CTs influenced whether patients were receptive or not to participating. These included patients’ beliefs about being a “guinea pig” or general orientation towards medical technology that was informed by their previous healthcare experiences, conversations with friends or family, cultural understandings of CTs, and social media. For example, a few patients expressed a fear of being a “guinea pig”, which they negatively equated with being experimented upon. This typically stemmed from their cultural understandings or personal or familial experiences of research experimentation as potentially exploitative. In contrast, other patients tended to view experimentation as advancing medical technology and as the answer to unlocking the mechanisms of disease and treatment. These patients perceived volunteering for a trial as heroic, which was supported by one patient’s spouse as something to “feel a little bit proud that maybe you can hopefully make a bit of a difference and help others after you.” Another patient with prostate cancer explained how he was thinking of CTs in relation to the social good:

Because like I say, I don’t mind being a guinea pig. If I contribute, you know, it doesn’t matter whether it’s successful or it’s failing. But if you don’t offer yourself to be part of this experiment, how could they tell the end result? In other words, the volunteer is very important, they need the volunteer to gain the approval. I mean the result is definitely through the data of the patient, right? (male, accepted)

Patients also described how their attitudes about trials were informed by their conversations with family or friends who had strong opinions about CTs. A close relative’s, friend’s or family member’s previous experience in a CT often informed whether a patient’s attitude towards CTs was positive or negative. Patients’ own previous CT experience or
beliefs about research also coloured their perspective going forward. One breast cancer patient discussed how her professional experience allowed her to gain an understanding of research and fuelled her initial positive appreciation of the study:

I also worked as a nurse in the research department at the cardiac department at [name of hospital] and they [studies] were all pharmaceutical ones. I was not impressed with all of them. So I don’t see all research as being for the best for everybody, but in general, I will say that, yes, I am particularly for breast cancer and other women’s cancers that the research is what helps move things forward so there’s better care and less toxicity and less damage to the person. So I’m willing to participate (female, accepted).

Another patient discussed her previous experience on a fitness trial for cancer patients and how she found it extremely positive, which informed her current decision about whether to go on a drug trial:

And then I would say I have had the luxury thus far of participating in a clinical trial that really had no downsides to it… there was only an upside, in my opinion, to participating in a fitness trial. And you know, it brings along with it a support group and everything (female, accepted).

The above quote illustrates how positive (or negative) previous experience can potentially mislead patients into thinking that all CTs are conducted in a similar manner. Therefore, it would be important for patients and oncologists to acknowledge previous experience but also focus on the details of the current CT being offered.

Patients’ beliefs and attitudes, previous CT experience and conversations with others influenced their degree of receptivity or how “open” or “closed” they were to receiving a trial offer. Rather than discrete concepts, patients’ level of receptivity existed on a continuum whereby some patients were adamantly closed to learning about CTs whereas other patients were very open. Those patients who were very open to CTs typically had positive beliefs and attitudes or previous healthcare experiences that encouraged them to orient themselves in this way. Some believed oncology trials represent the cutting edge of cancer research and were
generally more optimistic about studies having positive results and helping others. These patients may have actively sought out CTs or approached their oncologist about them instead of waiting for a trial offer. One patient discussed his feelings of optimism about participating in CTs:

I like to be on the leading edge. So far they haven’t found the magic bullet, but you do get this feeling of optimism when you know a lot of work and research has gone into developing these compounds, and you might be one of the first people to be taking it, so I generally feel sort of optimistic, knowing that when all else has failed, this might be the substance that will succeed in slowing down the growth of the particular cancer that I have. I go to them generally with a feeling of optimism for those reasons (male, accepted).

For some patients, social media, such as general news broadcasts, radio or television shows and newspaper articles, had a positive or negative influence on personal beliefs and attitudes towards CTs. For example, a few patients developed initial concerns about a trial’s safety after learning about drug-related side effects in a newspaper article. Other patients heard more positive messages about CTs. The following quote illustrates the power the media had in fostering a prostate cancer patient’s optimistic attitudes towards CTs:

Oh I think it’s [CTs] a marvellous thing because I mean every time you turned a radio on or turned the TV on, there’s always some new developments with cancer. You know, they’re getting a step up on this; they’re getting a step on that. Oh yeah, it’s very positive (male, accepted).

Patients who were closed to CTs typically had beliefs and values or previous healthcare experiences that caused them to be more skeptical of research and cautious about participating. Relating back to the core construct, these patients’ beliefs and values were, in turn, often influenced by their social network. For example, a family member might have had a negative experience in a CT (e.g., experiencing numerous side effects, received placebo) and passed along his or her anxieties to the patient in conversation about trial participation. These personal and social factors made patients more hesitant about taking part in a trial:
And my experience has been - not in the trials, I only did do one trial, not with the [name of cancer agency], it was a pain trial—when they said 2% of patients have these side effects - I had them all! Same thing when I would go for surgeries. Most patients tolerate this well but 2%...so I was always on that cusp of the bell curve, way off the other end. So I got to dislike the term ‘most patients’ and I got very weary of it because I learned that what I had to look for is what are these 2% side effects. What are they. And if they didn't meet my criteria, just out immediately. Period. And that was the basis of most of my readings. It wasn't that the trial didn't look good, the results looked good, the results looked promising. But I wasn't gonna trade side effects for the cancer. That was not my motivation (male, declined).

Patients’ initial receptivity was a powerful influence on how they then engaged with the trial offer and decision-making phases of the model, such as what and how much information was sought. For example, patients who were closed or skeptical of trials because of previous experience with debilitating side effects on a prior trial sought in-depth information about side effects for the current trial. In contrast, patients who were more open to trials had a broader interest in many aspects of the trial. Level of receptivity also provided an initial starting position for receiving and interpreting information. As one patient with breast cancer explained, her initial openness to a trial became her “default”, and all other information was considered in terms of whether it would give her a reason to reject her initial decision:

I just went through the thought process, is there any reason why I would decide not to do this, if that makes sense? I left with the default switch on I’m probably going to do this, and all the other stuff was just around whether or not something would move me off that position (female, accepted).

**Phase II: Trial Offer**

This phase of the model was complex and inherently relational. Patients interpreted the way in which a trial was presented and the demeanor of the oncologist in making a judgment about the relevance and value of the trial for them. For example, a patient with
breast cancer reflected on her oncologist’s clear presentation of the trial but believed her overall positivity reinforced her initial openness to participating in the study:

Well, I think she [the oncologist] was very positive about the studies. I think she was very fair in that it wasn’t presented in a manner that would have made me worry if I hadn’t gone on the study. Like, I don’t mean to make it sound like she over-sold it; she was very clear on the pros and cons, but she was very positive about it and I guess maybe that’s sort of the overarching element; she was quite positive that there’s this opportunity, you know… kind of discussion about who else and what else and where it was in its program and that it seemed to be a very well-tolerated drug and stuff. I think her positive approach and good initial descriptions kind of right away gave me a good feeling that, well, this is probably not a bad thing to do. I left with a positive feeling about it (female, accepted).

Another patient recalled how the positive presentation of a trial supported his initial openness to participating in the study. Reflecting on his decision, he acknowledged that potential side effects were not presented to him in a clear and straightforward fashion. He believed that if they were, this would have caused him to “think twice” about the trial and reflect more on the consequences of CTs, thus calling into question how informed was his consent to participate:

I was very eager to do these trials. And, in fact, with one of the trials I signed up before I read it. Probably not a good idea, but … Where do I sign? I think things were never presented to me in fear terms either. They were presented in positive terms. If somebody had approached me and said, ‘Here’s a great trial. You’re going to be sick as a dog’, I would have thought twice. But they were always presented in positive terms (male, accepted).

Some patients interpreted the mere mention of a trial as a recommendation to participate. This may have been partly a result of structural influences that created confusion between treatment and research, such as the CT presentation by the oncologist occurring during a patient’s regular clinic appointment. In one or two cases, oncologists were reportedly very explicit in conveying participation as a “no-brainer”, that the drug would be effective and recommending the patient participate. This statement supports the findings from the study with CT personnel, where patients were influenced by oncologists’ subtle and
overt “messages” about CTs. Most patients believed the oncologist was looking out for their best interests and appeared to extend the principle of beneficence that informs treatment decision making to the context of CTs. In other words, patients assumed the trial would not have been presented to them unless their oncologist thought it was a good thing for them to do:

In all of these doctors that I’d been seeing – I’ve got three; I’ve got my GP, the urologist, and the oncologist. In all three cases, I’ve come to embrace what they are saying as the truth, and I agree with it, and I don’t have any qualms about following their advice. I understand that they all have my best health in-, you know, it’s what they’re trying to do, is make me healthy (male, accepted).

The above quote highlights the relevance of the core construct driving the theoretical model. It appears that patients, although encouraged to demonstrate personal autonomy by making their own decisions, are likely to embrace relational influences on their decision-making processes. This is particularly the case given the nature of the patient-physician relationship and the vulnerability of cancer patients. What is striking in the above quote, however, is the potential for misunderstanding CTs as individualized medicine. This raises the issue of whether this patient was able to provide truly informed consent to participate in the trial and/or whether the patient was exhibiting well-placed trust in his physicians. These issues will be explored further in the discussion (Chapter Six).

Within the context of the trial offer, the majority of patients assessed their oncologist’s level of enthusiasm for the study in order to ascertain whether he or she thought it was a good thing for them to do. Was the oncologist excited about enrolling the patient in the trial or did he or she have concerns or reservations? Some patients outright asked whether the oncologist thought it was a good option for them, others were attuned to more subtle indicators that the oncologist seemed more or less keen, either through the physician’s body
language or non-verbal behaviour. One patient described how he “sensed” his oncologist
needed someone in the trial, which was confirmed for him through a handshake after he
agreed to participate:

> It took him about 20 minutes. He sat right beside me and he told me about this. And I
knew he—I sensed he needed somebody badly. [...] He sort of quietly talked to me
about it. I put money as I told you earlier on him and I said okay, I'll do it. And he
shook my hand warmly and said he was pretty happy about it. So he obviously
needed another patient (male, accepted).

Another patient was very attuned to her oncologist’s presentation of the trial and also
recognized the need for participant accrual if trials are to move forward. This sensitivity to
physicians’ attitudes and behaviours may reflect the perception found within the CT
personnel interviews that cancer patients often seek ways to please their oncologist to
demonstrate their appreciation for the care they have received. In this example, the patient
detected a heightened level of enthusiasm from her oncologist’s explanation of the trial,
which suggested to her that there was some bias towards her participating in the trial:

> The doctor wanted me in the trial very badly. They're trying to get their number of
people that they want in the trial. And she had a lot of information, explained to me
how they came about with their numbers and how many people were going to be on
either side and how it was chosen and this and that. So she was quite encouraging in
trying to have me take the trial (female, declined).

This patient ultimately decided not to participate because her current treatment was working
well and she did not want to take a new drug with uncertain risks and side effects. This
decision, however, was very difficult and she required the assistance of another doctor, who
encouraged her to trust her “gut instincts” and carry on with a treatment that had worked for
her in the past.

Although most of the patients I recruited into the study were offered a CT, during the
interview some participants reflected upon the implications of not being offered the option of
a trial. Patients believed this would immediately foreclose the option of trial participation and any further decision making unless the patient was to actively seek out a trial on his/her own. One participant did have the experience of not being offered a CT initially. She believed her oncologist made assumptions about her ability or means to travel to the study site, which was four hours away by car. Because this patient was actively searching for CTs, had no other treatment options left, and had advanced disease, she confronted her oncologist and asked to be enrolled in the trial. This patient was fortunate in the sense that she was well educated and had an active social network that assisted in her identifying a CT for which she was eligible, thus allowing her to overcome the gatekeeping behaviour of her physician. From a relational autonomy perspective, other patients who are in less fortunate circumstances in relation to socio-economic and social support factors may have been less able to advocate for themselves and confront their physician’s assumptions.

Finally, throughout the trial offer phase there was slippage between how oncologists and patients framed the trial. Sometimes the trial was referred to as “treatment” in the discussions, so it was unclear that the trial drug was actually experimental. As demonstrated by one oncologist’s general recollection of CT discussions:

But if patients, with that particular trial, they say to me, ‘well which do you think is the better treatment?’ And I’ll say ‘I think this treatment’s going to have better cure rates, but it’s going to have more side effects, and so you as a patient need to decide if you’re willing to accept the risks of more side effects for a better long term cure rate’ (emphasis added).

This lack of clarity encouraged some patients to consider the trial as potentially offering the best treatment option. This was particularly the case amongst patients who reported they had advanced disease and whose options were already limited. As shared by a prostate cancer patient:
I mean, that was a **treatment** option. I mean, surgery or radiation, those are all gone for me. So **trials, that’s great**. Go for it man, you know? What else am I gonna do? At my stage, it’s easy (male, accepted, emphasis added).

These quotes illustrate the potential for the therapeutic misconception and the possibility that patients are not making informed decisions about trial participation. These issues will be explored in greater detail in the discussion (see Chapter Six).

**Phase III: Decision-making**

Once patients were informed of the option of trial participation they then moved into a series of processes that made up the larger decision-making phase. This included seeking information, establishing credibility, and weighing pros and cons. Seeking information and establishing credibility were complementary and informed each other. The majority of patients moved back and forth between these two phases. Many patients then progressed to weighing pros and cons but returned to seeking information and establishing credibility if new questions arose. Other patients did not continue into the weighing pros and cons process. As will be described below, these patients went directly from seeking information and establishing credibility to making a CT decision.

**Seeking Information**

**Type of information sought.** Patients sought a variety of information that they believed was important for their decision making. For the majority of patients, physical effect was foremost in their minds. Patients wanted to know what their oncologist thought about the trial and whether the trial intervention would be effective in helping them survive their cancer. The likelihood of experiencing serious or unpleasant adverse effects, as well as whether participating would require prolonging or temporary stopping their current treatment, which could pose a risk regarding the spread of disease, was also valuable
information for the majority of patients. Consistent with the relational autonomy framework, the oncologist was also perceived to be very important for supporting some patients’ interpretation of the CT information, as demonstrated by one patient with breast cancer:

So reading all that stuff about the possible side effects, it is true and they have to tell you that, but it’s less of an influence than the conversation with your doctor. Because you need to be able to put some perspective on the likelihood and the severity of these [side effects] (female, accepted).

Whether the trial design involved a placebo and the chances that they would be randomized to a non-experimental agent was also information that patients prioritized in the information-seeking process. Other health benefits they might receive from the trial, such as closer physiological monitoring (i.e., extra tests and blood work), additional nursing support or follow-up care were also important. Similarly, understanding the logistics of the trial was significant so that patients could assess the potential burden on themselves and their family members. Logistics included how long the trial would last and how far and how often the patient would need to travel to the study site.

**Sources of information.** Patients sought information from their oncologists, CT nurses, GPs, fellow patients, and family. They also sought information from social media and, occasionally, scientific journal articles. After receiving trial information from their oncologists, patients typically went home and searched online for further information about the trial intervention. They used their social networks to direct them to relevant information, support them in distinguishing credible from non-credible information sources and help them assess the information they collected in order to situate it in the context of their own lives. This often entailed weighing risks and benefits in light of their personal and family goals and values. Thus, seeking information was a cyclical process where patients continually asked questions and sought further information to address gaps in understanding. One patient with
breast cancer shared how she consulted with her husband at multiple times to seek his
opinion and help her interpret information and seek further understanding, thus underscoring
the importance of close relationships in this phase of her decision-making process:

> I found news stories related to the study and then I found more scientific information
> about the study parameters, not that I fully understood everything or most, but it gave
> me a pretty good overview. And it was over a course of a week I would say I kept
> checking stuff on the internet and talking to my husband about it and so it was a back
> and forth (female, accepted).

Another patient, who declined a previous chemotherapy trial but accepted another subsequent
drug trial, described the advantages of involving others in the information-seeking process:

> Well, I process through talking. So just talking to people and then, you know, you’re
> kind of going down a path and somebody might point something out and you go, ‘Oh
> yeah, okay, I’ll think about that one’ (female, declined/accepted).

Some patients shared that they preferred to consult with healthcare providers to gain
assistance in interpreting information rather than seeking help from family members because
providers were viewed as the experts. This was particularly the case with some men, in
whom traditional gender roles and previous professional experience appeared to influence
information seeking behaviour. One prostate cancer patient stated the following when asked
about his involvement of family members in his CT decision:

> Oh, not very much. Other than the fact that I wanna be around 'em. I don't ask 'em for
> advice or anything. I'm kind of a patriarch of the system and I don't seek advice from
> anybody. I was a manager, six departments in a company, I had 200 people working
> for me. What the hell. You get used to making your own decisions without input
> (male, had both accepted and declined CTs).

The kind of information patients sought was heavily influenced by the type of CT
being offered. For example, with exercise trials, patients primarily considered logistics rather
than adverse effects because these trials were perceived to be generally less risky and the
objectives more easily understood. Drug trials, on the other hand, were perceived to involve a
“life or death” decision and patients prioritized information about the potential risks and physiological side effects. These trials also required deciphering complex information. As shared by one patient with breast cancer who made decisions about both an exercise and drug trial:

I think it’s a different decision to take internally a drug and participate in that kind of trial, than it is to participate in some time of external study, like the fitness trial, or I’ve seen ones to do with relaxation and other things like that. To me, those are different decisions. I think people in general have a better understanding of the outside-your-body ones than the inside-your-body ones, in that the inside-your-body one is really a black box for the non-medical person, right? You’re simply taking this drug and you don’t specifically understand the mechanism. For me, it was quite a different decision to go on a drug trial and it does just have to do with the… kind of the unknown effects on your body, perhaps (female, accepted).

**Barriers and facilitators to information seeking.** Many patients found the ease of the information-seeking process to be dependent on the “newness” of the experimental intervention and the subsequent availability of information. For example, patients were more limited in their search for information about experimental drugs in the first phases of testing because the human data was non-existent. On the other hand, if the trial intervention had been used previously to treat other cancer types or patient populations, or if it had already been subject to Phase I or II trials, then there was usually some information available to inform patients’ decisions:

I started out with news links about the study, because news links, you know New York Times, various papers had talked about the study. And then of course they would reference other sites as well, for more information such and such, you know how you hop around doing searches. And then after that I just brought up Metformin in itself and just started reading about it generally, trying to get a sense of what it was about. It was fairly easy to find information about the study. I guess because with three countries participating, there is a lot out there about it (female, accepted).

**Experience of receiving information.** The experience of receiving CT information varied across the cancer trajectory. Patients particularly struggled with CT decisions that
occurred around diagnosis. Fear and the emotional adjustment to the cancer diagnosis were identified as barriers to understanding information because it blocked patients’ ability to process information and appreciate how it related to their situations. In addition, there was often a sense of urgency surrounding the decision because patients did not want the cancer to advance. When emotions combined with the pressures of having to make a quick decision so as not to lose ground on fighting their cancer, patients expressed a sense of being completely overwhelmed and destabilized during the time when they were supposed to make a CT decision. One patient with breast cancer discussed her previous experience of declining a chemotherapy trial:

It’s a bit overwhelming …first of all, dealing with diagnosis, which is pretty traumatic, and then all the information around course of treatment and taking all that in. And then to be given an option for a study. That’s just another whole kind of…it’s all happening at once. And you’ve got to make the decision fairly quickly because you want to start treatment very quickly and then in my case, this time around, I started as quickly as possible. So yeah, it’s a lot of information to take in on that first meeting with the oncologist and so you’re dealing with all these issues and then there’s always that study that’s presented. And so it’s just more information to have to deal with (female, declined).

As a result, some patients appeared to limit their search for information because they were overwhelmed with information and just wanted to “get on with it.” As shared by a patient who received a drug trial offer shortly after being diagnosed with breast cancer:

I had already been inundated with stuff from going through my surgery and everything and the biopsies…it was already so much stuff coming that by the time I got to this it was like, ‘Yeah okay, just sign me up’ (breast, accepted).

Having had cancer before, being educated (some university or college level education), or having worked in a profession that required assimilation of complex information and navigation of risk probabilities may have helped some patients to manage their fears and consider CT information within their current context. Those whose cancer was
recurrent had some familiarity with being diagnosed and reported being able to
simultaneously process information related to their diagnosis and the trial option. Patients
who worked in healthcare, or had jobs that involved mathematics or science, also appeared to
be at an advantage to understanding risk information, which was often expressed in statistics.
For most patients, consistent with the “No Wo/Man is an Island” model, having support
persons available to also ask questions and take notes during the trial offer and review online
literature to filter useful information was a facilitator of patients’ information-seeking
processes, especially for those patients who did not have previous cancer experience or
professional expertise. As one husband who was a scientist stated, his role was to help his
wife “figure out what she wanted and to make sure that she knew that whatever she chose
was okay with me.” This man supported his wife’s relational autonomy by not telling her
what she should do but rather by helping her seek appropriate information that was relevant
to her goals of treatment:

I think to give as much information as possible and easy sources of information for
further understanding for those who what that would be helpful. I happen to be able to
surf the web and have a scientific background so I could find the studies and we have
people in the family [who could review the studies] (male spouse, supported female
patient who accepted a CT offer).

Lastly, some patients expressed feeling “sheltered” from certain information by health
professionals or not receiving the information they felt was important to their decision
making. This was perceived to be a result of oncologists withholding or not elaborating on
information related to severe adverse effects, including mortality rates, because of the
concern that such knowledge might cause patients distress. A few patients were sensitive to
CT personnel’s struggle to provide the necessary information while minimizing their fears,
which was supported by the perspective of a few prostate cancer patients who did not want to
know certain information about their life expectancy, for example. However, other patients expressed a desire to be provided this information because they felt it was important to their decision making. As discussed by one patient:

Now I do believe at the time I got some information on the drug and its side effects and [the oncologist] certainly pointed out it was a Phase II drug experimental program. But he didn’t say how many patients failed and have since died or anything like that. That would have been the information I would have liked to have known but that may have scared me away, so… (male, accepted).

The above demonstrates the interesting ethical dilemma of CT personnel not wanting to share information that will cause patients to experience additional anxiety or fear but still needing to support patients in making fully informed decisions. This issue will be discussed more fully in the final discussion chapter (see Chapter Six).

**Establishing Credibility**

Most patients engaged in a process of establishing credibility or trustworthiness as they sought information about a CT. This was largely a social process that required input from others. Patients attempted to determine the credibility of not only the oncologist presenting the trial, but also the institution hosting the trial and the drug or company sponsor. There was a circular relationship between the process of seeking information and establishing credibility. In order to establish the credibility of an information source, such as a health professional or a clinical institution, patients had to first seek information about their reputations. Was the oncologist a leading scientist in the treatment of their cancer type? Was the institution a world-renowned centre for cancer care? In this way, patients’ relational autonomy extended beyond the patient-physician relationship into the organizational and structural context. Once credibility was established, patients described feeling more confident in seeking further information about the CT from these sources.
Establishing the credibility of their oncologist, who patients believed also had a role in recommending trials, was especially important to patients since these physicians were their point of care for cancer treatment and patients relied upon them for psychosocial support. Patients established credibility of their oncologists in several ways. Some patients turned to a physician whom they already trusted (often their GP) to recommend a reputable oncologist. The GP would “bridge the credibility” by identifying the oncologist as a leading expert in the field of research and treatment of the patient’s type of cancer. Credibility provided patients with the foundation for the development of trust in their oncologists. Some oncologists, in turn, earned patients’ trust by investing time and energy into building a caring relationship with the patient and family, and going above and beyond in their care. One patient described how her oncologist, whom she believed to be credible and well-respected in her field, also treated her as an individual and made her feel cared for and well looked after, thus enabling a trusting relationship:

She was very open, she was so warm and so confident and I liked the fact that she was straightforward, I could ask her anything, she called me late at night - it surprised the heck out of me! I’m in bed and I get this phone call…it was actually her calling from home, so stuff like that. She always asked about my kids and so it wasn’t just…I wasn’t just another number or just another person, and I know how busy she is, so I hate to take up any more of her time, but I appreciated that relationship with her. And knowing who she is, that to me meant a lot too. That I could trust her (female, accepted).

Trust was important because it made patients feel safe and that their best interests were being looked after. Patients who trusted their physicians were more likely to seek their physician’s opinion and recommendation regarding CTs. Only a few patients were able to trust their oncologists without any history of relationship or recommendation from another physician; however, these patients often had a medical professional in the family and were
thus “more open to the concept of trust my doctors and off we go, kind of thing” (female, accepted). As another cancer patient with breast cancer stated:

I trust my healthcare professionals. I’ve been lucky enough to have very good people treating me over the years and so if you start with that level of trust, then if it’s something they suggest, obviously that carries a lot of weight. And I followed pretty much all of the suggested treatments that I’ve been offered and that’s again because of that level of trust. These people are the experts and they know what’s best for me. I mean I don’t follow everything unquestionably but that certainly carries significant weight with me and so the fact that [name of oncologist] thought this was an important study – it was the same thing, it carried a lot of weight with me (female, accepted).

For some patients, establishing trust in their oncologist was an “essential” component of their CT decision-making process as it allowed them to accept their oncologist’s opinion about the trial and bypass some of their own decision-making processes. These patients are called “snap” decision-makers in the “No Wo/man is an Island” model because they privileged the doctor’s knowledge and thus spent less time specifically on researching information and weighing pros and cons. Some snap decision makers appeared to blindly trust the oncologist to know what was best for them (often their trust was based primarily in oncologists’ social authority and professional status), while others had spent more time establishing the trustworthiness (and credibility) of their oncologist through their social networks and structural resources. For example, one male patient asked his cousin, who was a researcher at the cancer centre, to confirm the credibility of his oncologist. Once the patient had his cousin’s confirmation, he proceeded to trust his oncologist and made a snap decision to participate in a CT.

In general, patients recognized their oncologists as specialists who had far greater knowledge, skill and expertise regarding cancer treatment decisions than they could ever have. They also assumed their oncologist would carefully consider their case and would not
recommend something that would harm them or not be worth their while. As expressed by a patient with prostate cancer:

I had the information that I wanted and that information sort of manifests itself in a trust of the people that have been treating me at the cancer agency, so I already have a fair amount of information on those people and I trust them, so that work is done. I know that, as specialists, if they think it’s a worthwhile proposition to test a drug on me, I don’t for one minute think that they are doing that or make these decisions not without thinking about them fairly carefully and coming, first of all, to the decision that it’s the right thing to do. I am fairly sure that if they know of something out there that would not be effective in my case, then they wouldn’t offer me the treatment. I am fairly confident that the clinical people look at my case and look at me as an individual or my disease as an individual phenomenon and decide what is worthwhile trying and what is not (male, accepted).

The process of establishing credibility of the institution hosting trials also involved seeking the opinions of others. Patients sought opinions and reassurance from family members, the media, or GPs that the cancer agency was a centre of excellence or a “world-renowned” research institution. One patient discussed how he consulted with his family, who had previous experiences of being treated for cancer at the centre:

I actually spoke to my mother about it, and my brother. My brother actually went through the prostate clinic. And that’s how I ended up here, actually, is just through his coaching. And then I spoke to my mother about her experiences with breast cancer, her clinical trials. […] And my brother has got a fairly high regard for the clinic itself and sort of coached that if they’re conducting trials then it’s probably … it’s probably state of the art kind of treatment, I guess (male, accepted).

With regards to establishing the credibility of specific trials, some patients wanted more information about the study, including whether the trial was multi-site, how many subjects had been enrolled in the study to date and whether the intervention had shown previous success in other disease sites or cancer populations. If a drug had already been approved for use in another country and was in a later phase of testing in Canada, for example, this satisfied patients that it was credible and relatively safe.

It's been around for 40 years, so it's not something brand new that hasn't been
adequately tested in clinical trials for the other purposes for which it's used. So, presumably they've figured out all the negative problems that it can have otherwise it's just generally in your system. So it's not like you're taking something brand new (female, accepted).

**Weighing Pros and Cons**

A variety of sub-processes made up the complex weighing pros and cons process, depending on what concepts/themes patients prioritized as important considerations of trial participation. These sub-processes included doing what is right for me/considering altruism, weighing adverse effects and benefits, grappling with uncertainty, considering logistics and maintaining relationships. These sub-processes often overlapped, with patients engaging in many of them at any given point in time. Whether patients considered the concept as being a pro or con appeared to be induced by influencing factors, predisposing beliefs and/or social networks.

**Doing right for me/Considering altruism.** Many cancer patients considered whether the trial would benefit them or benefit others - *doing what is right for me* or *considering altruism*. To what extent patients were internally (self) or externally (other) oriented depended on a variety of factors, such as their stage of disease or pre-disposing beliefs and attitudes about research. For example, patients with more advanced stage of disease in this study appeared to be more internally focused on their own health since they are facing their mortality.

**Doing what is right for me.** The concept, *doing what is right for me*, involved assessing one’s needs and prioritizing the self. Prioritizing the self meant thinking of one’s own health status and emotional needs first, instead of others’ needs (e.g., social good), in order to fight the cancer. Typically, patients who prioritized themselves were aggressively seeking treatment for advanced or recurrent illness or they had just been diagnosed with
cancer and were focused on finding a curative treatment. Often, *doing what is right for me* was equated with a hope for a cure. One patient shared the following:

> I was motivated by the fact that I thought that this could really help me. That's what I was motivated by more than anything else. There really wasn't even a secondary thought in my mind. I thought this might be a hope for me (female, accepted).

A CT nurse confirmed that this self-focused orientation was not necessarily “selfish” but was a result of wanting to extend life. It most frequently occurred when patients were scared, had severe disease and when they had limited remaining treatment options. These patients were perceived as prioritizing themselves as they needed to find a treatment that would work for them because they wanted to live; however, being selfish could also mean refusing a trial because the burden was too great. As explained by a CT nurse:

> Often they’re facing large risks. They have either huge cancer and that is scary and has potential for coming back very fast and so they are looking at aggressive treatments, or they metastasized and there’s nothing left. They’ve got nothing else to try, they tried everything and like then, they’re at their wits end, they have nothing else. So those are the things that motivate people to think of clinical trials.

Many patients considered what was best for them in the context of their family. Patients wanted to be around for their loved ones. Some felt they were also needed to support raising children or to provide financial assistance. In turn, the patient’s family was invested in helping their loved ones find the best care available to extend their lives. Thus, *doing what is right for me* could be interpreted through a relational autonomy lens as *doing what is right for the family*. As one patient stated: “Well, it's because of my family that I chose to do this. It was to give me the hope of a little bit of life extension” (male, accepted).

Some spouses of prostate cancer patients went so far as to make the decision for their husbands or strongly encouraged the patient to participate in the study so that he would receive the best medical care. Thus, choosing a trial to receive the best care for oneself was
sometimes the responsibility of a family member. The tendency to strongly influence CT decisions was perceived by a CT nurse to be gender specific:

I think certainly for the men with prostate cancer, their wives and family and caregivers, the primary caregiver, has a huge impact on that decision. More often than not—this is my bias—the wives tend to push the husbands into doing clinical trials and kind of actually help make that decision for them. More often than not, they actually do push I think for the patient to go on study. I used to do breast cancer a long time ago and I found it was different for a woman. The woman made the decision and men were usually not there and usually did not make any comment.

**Considering altruism.** The concept of considering altruism fits well with the “No Wo/Man is an Island” theoretical model, since it is not just about serving the interests of the individual patient but also the good of society that is important in the CT decision. These cancer patients were primarily motivated to consider trial participation because it might help future cancer patients and contribute to the scientific advancement of cancer treatment. They held the belief that they would not currently be benefiting from drug therapy if patients before them had not volunteered for research. A few expressed a sense of obligation about “doing their duty” (breast, accepted), perceiving trial participation to be a “good thing to do” and a way to give back to others and advance science. As one patient with prostate cancer who had participated in many oncology trials stated:

The only reason I went on it [CT] was 1): I don't believe people don't go on it. It's kinda their obligation. If they have cancer and they're benefiting from experiments done before they got on a drug, then they should carry it forward and help someone down the line when their time comes. So that was the main thing I considered. Other than that, there's nothing else to say, you know? I just thought that it should be done. It's a good thing to do (prostate, accepted).

Patients who reported their cancer as localized, stable, or in remission were more often motivated to consider trial participation for altruistic reasons. These patients were typically less in a state of crisis with regards to their disease stage and illness management. They also believed strongly in the value of research. Patients who reported they had
advanced cancer but were not aggressively seeking further treatment were also more likely to consider trial participation for altruistic reasons. These patients were generally older and less concerned about outcomes or achieving their goals because of their later stage in life. As one patient reflected:

When you're 88½ years old, almost 89, you've had enough of this life, so it doesn't matter if it kills you. I was very successful in my life. I've had a good job, I got a house that's inflated by $100 a day in [name of town] and my kids will be well off, so what the hell (prostate, accepted).

Education level also appeared to play a role in patients’ ability to understand the purpose of research and to identify with the larger goal of helping others benefit from advancements in science. Those patients with university/college-level education and higher, tended to have an easier time understanding the role of research in informing standard treatment and that ultimately someone needs to volunteer to participate in research in order for care to advance. The following quote highlights how an educated woman with breast cancer was able to reflect on the purpose of CTs:

On the other hand, I figure that, with the treatments that I've had, I've benefited from a whole bunch of work that's gone on before. And I know that the only way that the doctors and scientists can properly assess a given treatment, is to do the randomized double blind medication, placebo or whatever they're testing to see if, in fact, it does make a difference. From a scientific standpoint I understand the concept and why they do it, the way they do it and why it takes time (breast, accepted).

Personal benefit and altruism were not mutually exclusive considerations. The majority of patients who were motivated to help themselves were also concerned about helping others, and *vice versa*. Patients often talked about framing these as primary and secondary motivations:

Well, very selfish initially. But then after you're chosen you think, ‘Oh yeah, and plus I'm doing something for the world of research’ (prostate, accepted).
A few patients stated that they experienced a moral struggle between doing what was best for them and what was best for society. This moral struggle was most pronounced in female cancer patients who expressed distress and guilt when they prioritized their needs and declined a CT:

Oh gosh. I just remember having such a tough time...There’s a huge part of me that wants to do the right thing and contribute to science and all that stuff. So my natural tendency is to go for these kinds of things. [But] there was an aspect of it that was kind of throwing my lot into sort of that randomness of...so that was drawing me away from the study and that’s in the end what made me not participate was the randomness...the big possibility that I was going to be, you know, kind of at the toss of a coin as to whether I had chemo or not (breast, declined).

However, it is unclear to what extent their distress was the result of an internal moral struggle versus a social imperative stemming from gendered norms and expectations. Social relationships had an impact on these female patients’ experiences since the way information was framed by CT personnel appeared to impact their levels of distress or how they perceived CT information.

**Weighing risks and benefits.** For most patients, weighing the risks and benefits of a CT was extremely salient to their decision-making process. Of paramount concern were physiological risks. These included the risk of disease progression if patients decided to stop their current treatment in order to participate in a trial or potential adverse effects of the study drug, especially organ failure, blindness and chance of death. These effects were considered by both those who accepted and declined CTs:

Well, the key thing is the side effects and potential side effects of the drug. They’re not particularly nice drugs so ... the probability of the down sides, or side effects, I guess tried to weight that. That was probably the biggest thing (male, accepted).

The most important thing was that there would be no side effects regardless of their statistical significance. As an engineer and so on, I know statistics very well and I know that they have their uses for selling and they have their misuses as well. I just have no interest in statistics that involve side effects. Serious ones. I'm not talking
about, you know, headache, diarrhea, that kind of thing. I'm talking about where you could have kidney problems... (male, declined).

Patients considered the probability and magnitude of adverse effects and to what extent their quality of life would be affected. This was very much a personal and individual judgement but often had relational implications. For example, a few patients had planned to travel with their spouses after cancer treatment. They did not want to participate in a trial that could cause them to have adverse effects because it could interfere with their travel plans. Also, fatigue was a significant outcome for some patients because it meant not being able to engage in activities that were important to them. As explained by a prostate cancer patient who initially was closed to a CT and declined participation because of adverse effects but later retracted his decision after talking with his oncologist about fatigue:

He [the oncologist] told me that I'd have no problems but fatigue. And I don't want fatigue and I have a hobby of collecting and I spend 10 to 12 hours a day on my computer, sortin’ those entries and I don't want any interference. So he guaranteed me that I would only have a little bit of fatigue (male, declined/accepted).

Perceived benefits of CTs that patients described as being influential to their decisions included improved access to new and state-of-the-art therapy that could potentially be effective for treating their cancer. This was particularly beneficial because of the current restrictions to new drugs in the healthcare system that made CTs sometimes the only way to access a therapy. A positive by-product of trial participation that many patients also commented on was access to additional nursing support, follow-up care and tests to monitor their physical health. Many patients appreciated the idea of continuous health monitoring while on a trial and saw this as helping them cope with the fear or anxiety they had about cancer spread or recurrence, particularly once standard treatment ended. As mentioned by one breast cancer patient:
To me, I find it a reassuring thing to participate [in CTs] because it’s getting me probably more oversight, somewhat more oversight than I’d otherwise get in terms of my breasts to make sure – because obviously a concern I have is that it will recur. So if I’m getting looked at more frequently as a part of participating in the study, I see that as a good thing. And continuing to get more attention to my condition. I find that comforting (female, accepted).

Follow-up care by nursing staff and monitoring was especially important for some patients who had previous experience with care that was fragmented. Returning to the “No Wo/man is an Island” metaphor, patients shared stories of being primarily an “island” or left to themselves in their experience of health care. Having to see several doctors and residents within one appointment, wait several hours for blood work to be completed and travel to different sites to receive test results often made them feel alone and unimportant. The lack of coordinated care experienced by some patients led them to view CTs as offering coordinated and comprehensive healthcare that they could not get outside of a trial. One patient explained this perceived benefit in the following manner:

So navigating the system is really challenging. And being part of a trial, being looped in to a nurse who navigates that system for you is awesome. It’s really awesome... also knowing and understanding that being part of a trial, you have a stronger link with the system because of the study nurse and just being able to have access to queries and questions (female, accepted).

The benefit of being closely monitored and receiving additional follow-up was particularly important to patients who lacked family support or did not have family living nearby. In other words, CTs provided the social support of being at the clinic and in frequent contact with nurses. As one breast cancer patient shared:

It was that I was going to get probably the best treatment that I could get, meaning probably a few more tests that would probably take a little more time for me, but to me it was like there was nothing that was going to missed, it wasn’t like oh well maybe we should have done this, I knew I was going to be followed through the whole procedure step by step, and that was really important to me because I felt I don’t have any family here, so it was more important that I had all the treatment I could get and know that I was being looked after (female, accepted).
Perceptions about the efficiency of the healthcare system also played a role when patients, especially those newly diagnosed, considered the risks and benefits of CT participation. One patient explained how she thought participating in a CT would address her concerns of long waiting lists and delays in receiving treatment.

When I found out I had cancer, of course that was the first thing, ‘Oh my God, am I going to be on this huge waiting list? How long is this going to take?’ and this thing is growing and the trial was going to start right away, so that did influence me. Because I was going to get my treatment right away, it was going to start right away. I don’t know if it would have been right away without the trial, but in my mind I thought the trial would be my best bet of getting the best medical care. (female, accepted)

It is important to note that in describing her experience, this patient appeared to equate receiving a trial intervention with treatment for her cancer, thus also raising questions about her level of understanding the difference between standard care and research.

In some instances, patients also considered the benefit of satisfying a sense of personal responsibility to be doing absolutely everything to treat their cancer. This would allow patients to avoid decisional regret. As one patient elaborated:

Again I think a couple of things, one was that I didn’t want to have to look back on my decision and wish I had done this, because that would have been the easier way of doing it. I knew that the clinical trial may be a little more time consuming and I didn’t know another option that I…I know there was an option, yes, I could do it, or no, I couldn’t, but I couldn’t imagine not doing it because it was going to give me, again the best care…just getting all the tests and having everything sort of put through quickly… (female, accepted).

In weighing risks and benefits, some patients whose current treatment was not working considered a CT because it would give them access to a novel and potentially life-saving medication, even if there was a chance they would experience adverse effects. These patients downplayed the potential side effects of participating in a CT by comparing them to the adverse effects associated with any chemotherapy treatment, thereby interpreting those
from the study as “not a big deal” or explaining how it is “part and parcel” of CT participation. The following patient was aware of the risk of placebo but focused more on the adverse effects of receiving the study drug:

If I did do this study, I had a 66% chance of accessing this drug, ‘cause it was two-thirds, one-third for this study that I’m on now. One-third placebo, two-thirds the drug. So I was, yeah, I really wanted to have this medication, again, because it’s my nature to go for it and do everything that I can do to stop this cancer. And so it was my only way to have access so this medication was to participate in this study. So I didn’t see any downside, apart from that, you know, small chance of having a significant reaction to the drug, but that was just a chance you’ve got to take (breast, accepted).

For some patients who were undecided about participating in a trial because of concerns about adverse effects, being informed by their oncologist or CT personnel that they could withdraw at any time was an important consideration. Other patients were aware that a trial had to be stopped if significant adverse effects were identified during the study, as discussed by one patient with breast cancer:

I guess maybe the side effects, or like whether you’re taking something that you later wish you hadn’t. I feel quite confident that… that’s not a big concern for me, in that I feel very confident that if there were any negative side effects, that these would be identified early and we would be all asked to stop doing it [the study] (female, accepted).

Clarifying the potential risks and benefits of participating in a CT was a process that for some patients occurred over an extended period of time. These patients returned to the information-seeking process, consulting with their oncologist or CT personnel about the potential risks and benefits. For example, the following patient identified delay in treatment as a concern for him but after talking with his oncologist, he was persuaded that the risk to his health was not significant:

I basically weighed the pros and cons, the upside and downside. When I was talking to Dr. X and he was explaining what it was … I was a bit concerned because the operation was delayed for four months, that was potentially a downside. And so we
discussed that and he explained, basically, the theory and the mechanism, what was going to happen. So when I was first speaking with him…decided there wasn’t much of a downside” (male, accepted).

**Grappling with uncertainty.** Unique to CT decision making (as opposed to treatment decision making) was patients’ heightened sense of uncertainty associated with trials and the influence this had on their decision-making process. There were many unknowns associated with these studies, which was precisely why trials were needed – to answer outstanding questions about an intervention’s safety and efficacy. Moreover, in order for trials to be conducted ethically in Canada, clinical equipoise must also be met (CIHR 2010). That is, the community of oncologists must be in honest disagreement about whether or not the trial intervention will be helpful, harmful, or no different than alternative treatment options already available. From the patients’ perspective, the fact that so much was unknown presented a challenge to their decision-making. Answers to questions that were important to patients were difficult to arrive at with certainty. For example, which adverse effects, if any, will the patient experience? What is the likelihood of benefit from the intervention? If it is a placebo controlled trial, will the participant receive the active arm or placebo? If the patient forestalls standard treatment to be in the trial and receives the placebo, what is the chance the cancer will progress or recur?

Patients’ uncertainty about an intervention’s effectiveness and safety was more pronounced for earlier phase trials because so much more was unknown about the intervention and outcomes at this stage of testing. There was also little to no expected benefit to participants, including a risk of receiving no intervention. Some patients managed this uncertainty by seeking information and establishing credibility of the study drug. For example, if the trial had been conducted in other countries and had shown promise in earlier
phases or for other diseases, then this assuaged some patients’ anxieties about the unknown efficacy of the intervention or fear of adverse effects. One breast cancer patient described how her familiarity with a study drug for treating diseases other than cancer allayed some of her fears about unknown side effects:

And with this Metformin study that I’m going on, for example, I was quite comforted to know that it is a well-established drug from other fields of application, so there’s quite a long history of its application. If this was a drug that only had two years of people taking it, then I would be a little bit more concerned about unknown consequences twenty years from now (female, accepted).

Patients grappled with uncertainty and ultimately managed it in one of two ways: either deciding to **stay with the tried and true** treatment, thus declining to take the risk of the unknown associated with CTs, or rationalizing they had **nothing to lose** if they accepted the offer to participate in a CT, thus facing uncertainty head-on. Patients’ perceptions of illness severity and their previous or current healthcare experience (e.g., if patients were already taking a known effective treatment) influenced whether patients were willing to take the “gamble” and try something they really did not know much about. Patients who were motivated to stay with the tried and true treatment shared that they felt that standard care was the most effective course for them because they believed their cancer was, for the most part, under control. As a result, they were less willing to take a risk where they could experience unpleasant side effects in the face of uncertain benefit. As described by one patient:

That was basically my thought process was going through what I could expect from the different choices. And again, deciding to **go with the tried and true** rather than take chances on something that might give me horrible side effects that I wasn't quite...my argument had always been it was a matter of whether I was going to go through with any treatment at all was the quality of life that the treatment would allow me. If I was going to spend six months flat on my back sick to have an extra six weeks of misery at the other end then I would have said, “Thanks, but no thanks” (female, declined, emphasis added).

Another patient described how her understanding of the severity of her illness influenced her
decision to continue with standard care:

Because at that time, I did not have metastasis and so I would look at what was the best treatment options and what was the best success rate, and I would rather go with something that I knew than something that I didn’t know (female, declined).

On the other hand, patients who reported they had late stage disease and fewer treatment options perceived they had nothing to lose by venturing into the unknown. In these cases, patients downplayed the risks of a CT and hoped the extra tests would at least lead to early detection of cancer progression that would help inform their oncologist’s treatment plan outside of the trial. These patients framed uncertainty as a potential benefit since there was also a chance the intervention could be helpful. As both a breast and prostate cancer patient explained:

And so I would probably have wanted to be more ill to participate in that trial than me currently feeling perfectly healthy. I probably would have been less willing to go on one where I didn’t have as good a view of what the likelihood of an unknown effect on me was. So I imagine, in a way, the more ill you are, the more embracing you are of the unknown, because there’s also the unknown upside too (female, accepted).

Of course, you know what we get into but then you have to pay a price. Paying a price is getting into the unknown, getting into uncertainty. And there’s no guarantee. But again, the final, I think the rationale is no venture, no gain. If you don’t get into it, then you don’t know what happens (male, accepted).

**Considering logistics.** The majority of patients considered the logistics of trial participation as part of their decision-making process. This sub-process also relates back to the core construct in the sense that patients are whole persons. They have lives and responsibilities that they need to consider in addition to their disease and whether the trial is the best option for them. Patients reflected upon the amount of time that would be required for them to attend the trial, how many visits they would need to make to the cancer agency and how long the trial would last. Driving to attend clinic appointments was a major concern for many patients who were considering trial participation as well as whether they could
afford the cost of parking and fuel, which could be significant, especially for longer trials that required frequent visits to the agency. Even those patients taking advantage of volunteer driving services had to consider the associated challenges:

Initially, it was quite a commitment because I had to come in every week and then… Yeah, I think it was every week or every two weeks initially. And so that was time consuming. So, it was a matter of arranging rides and volunteers to help me come in, because at that time I was still quite weak, I wasn’t coming in on my own. And so that was certainly a concern, but felt that once we go through that then just coming in once a month was manageable (female, accepted).

Most patients relied on family or other support persons to drive them to the clinic. This was particularly the case for patients who lived outside the city centre. From the perspective of these patients, much coordination with their social network was required in order for them to participate in CTs. They needed to request certain appointment times to fit with their driving schedule. They also needed to deliberate about how best to manage their fatigue after a long day of travel and appointments. For some out of town patients, they had to rely on family members or friends to provide a place to stay over night, if required:

Because we come in from [name of city], I had requested morning appointments for the fact that I come and stay at my sister’s place because from her place it’s a half hour drive. From [name of city], it’s a two-hour drive. It’s a lot more relaxing for me as well too because if we have to drive in for two hours, you get here, you’re tired. Then you see the doctor and you get your prescription, whatever, then you turn around and drive back home again. I mean that’s 200 kilometres in one day. So I mean that’s a tiring day. And so that’s why I made the arrangements with my sister to go and stay the night before (male, accepted).

Patients were concerned about the time that they would need to dedicate in order to participate in a CT and whether they would be able to fit it into their daily lives. Many needed to negotiate flexible work hours and childcare in order to participate. Particular challenges existed for those younger patients who were still working and had children at home that required care. As explained by one patient with breast cancer:
It was not close to home for me, so travelling back and forth to downtown was a lot…
it was just the time and making sure I had child care because a lot of it couldn’t just be a short appointment. Even though I would be here in the morning and my kid would go to school, but he would be home at noon, so I always had to make sure I had somebody covering that. So that to me, that was the only real issue, was the travelling back and forth (female, accepted).

Those who worked for employers that allowed some flexibility regarding work hours were more able to commit to trial participation. Other patients were able to go on disability or were retired, so balancing work with CT participation was not an issue. As one patient explained:

I don’t work anymore, so maybe you should make a note of that. It would be a lot harder if I still had kids at home, in school or I was still working full-time. I used to practice as a lawyer. So I don’t have as many demands on my time. I do some not-for-profit board work and that’s about it. And so, that’s probably another big factor in my participation, is the fact that I do have more free time than the average working person or working parent out there. So I thought I don’t really see why I shouldn’t participate (female, accepted).

Although some patients might have been able to negotiate time off work, there still was the issue of lost wages if they needed to be absent for long periods:

I’m very lucky, because I’m self-employed – I run two businesses – so those businesses were capable of running on their own if I needed to be away. I was away from work for quite a bit during the chemo, especially. The radiation not so much – it was very easy compared to chemo. But yeah, they could run quite well without me, so I wasn’t… that wasn’t a concern. And I didn’t have to worry about money. I imagine for some people that’s a huge, huge thing (female, accepted).

In addition to the above logistical issues, some patients described feeling overwhelmed just managing their standard treatment regimes. Further coordination of a CT would have meant more visits to the clinic and even more coordination with their social network. Some patients did not have the economic and social means to coordinate visits to the cancer centre for trial participation, thus raising the issue of inequitable distribution of resources across patient groups. Even though the study intervention might be beneficial, one
breast cancer patient explained that she felt the chances she had of actually receiving the active arm was not worth the added inconvenience because coordinating her participation in the trial would be difficult:

I had heard positive things about taking the bisphosphonates but I only had a 1 in 3 chance of actually landing that in the clinical trial and I thought for all the pain and effort… the inconvenience of going in for all these extra tests and things. I was having a hard enough time going in for the tests I needed to just follow up on the chemo. And then parking and, in some cases, having to get people to drive me. I had my plate full already with just getting to my chemo treatments. It was just too logistically demanding and difficult under the circumstances I was in at the time (female, declined).

A few patients spoke about prioritizing other activities that they perceived as being more important to their quality of life than visiting the cancer agency for a trial:

No, I was asked if I wanted to participate in the sports one, which I would have liked to have done, but you have to go I think two or three times a week in town and during your chemo for it and I thought since that got into the summer – actually it was longer than May, June, it was May, June, July, August. What am I thinking? It just got – life into 3-week chunks at that point. We have a place [outside of town]. Psychologically, I really wanted to be able to escape to there between my treatments. So if I had participated in the sports study, I wouldn’t have been able to have gotten out of town for the summer, which was really important to me (female, declined).

Patients identified ways in which CT personnel addressed logistical challenges to their participation in a trial. If the trial tests and follow-up were incorporated into already scheduled clinic appointments for standard care, then this would lessen the additional logistical burden of CTs. Also, if CT personnel scheduled appointments for when it was most convenient for the participant to attend, thus working around the patient’s schedule, this also facilitated patients’ participation. As described by one patient:

I asked about how it would impact my time and would I have to do extra things and would I have to be at the clinic more often…all the logistics of it. I didn’t have to do anything different. I had more blood tests done, I had more blood taken and that sort of things and that’s what she had told me initially, but she said that would happen on days that you have to be here anyway. So that part of it was very convenient for my life (female, accepted).
Logistics, however, were balanced against perceived need and limited treatment options, especially among those with more advanced disease. For example, patients who reported they had late stage cancer were adamant that just because they lived far away from a study site, CT personnel and oncologists should not assume that they would not want to participate. As one patient explained, advanced illness creates pressure to make logistics work - the cost and inconvenience of travel is minimal compared to the possibility of death from advanced illness:

> It is a serious business, terminal illness, and if I think that I could have advanced my position, or in fact retreated from terminal illness one inch, by making several trips across town and having several bone scans, I will do it. It is an easy decision to make (male, accepted).

Another patient, who discovered her oncologist had not offered her a trial because of assumptions made about her ability to travel to attend appointments, was very concerned that she was not initially presented with the option. The following quote highlights the potential for oncologists’ assumptions to result in inequitable access to CTs and potentially damage the trust relationship with patients. Furthermore, as the following quote demonstrates, it is a mistake to assume all patients are only “islands” unto themselves, and not integrated with a socio-political system that can potentially facilitate their access to CTs:

> So I did all the background information myself and when I told her about it, she was like, ‘Well, it's in [major city].’ I'm like, ‘Yeah, I know. So? You should at least have offered it to me.’ You don't know what my financial situation is. You don't know if I have family there. You don't know anything. I do have a lot of support. I used to live in [major city], I lived here for six years so I have lots of friends. I am lucky that way. But she didn't know that when she didn't offer it to me. It makes me wonder if there's other people that could possibly take part in it that are in other cities, that their oncologists just don't tell them about because they think that they wouldn't travel. Do you think someone wouldn't sell their house if they really felt like they were—you know what I mean? People will do whatever it takes (female, accepted).
Maintaining Social Relationships

**Familial relationships.** The nature of cancer and cancer treatment is inherently relational because of the significant impact it also has on the family who are often accompanying patients to treatments and supporting them at home/in clinic. As such, patients had to consider the impact of CT participation on family members. Thus, the sub-process of maintaining social relationships demonstrates very pointedly how no patient was simply an individual unto oneself (e.g., “No Wo/Man is an Island”) but that patients were situated within a social network that could easily be affected by trial decisions.

Considering how trial participation would impact family members both emotionally and logistically was an important influence on patients’ decision-making process. Many patients spoke about heavily relying on their family for support throughout their cancer experience. For example, families or spouses accompanied patients to clinic appointments, provided help with patients’ understanding of their diagnoses and treatment options, were significantly involved in taking notes for thinking through options or offering their opinions/recommendations, as well as provided much needed emotional support for dealing with patients’ distress and logistical assistance for attending appointments. Thus, most patients were concerned about the impact of trial participation on their family and felt the need to assess whether family members were prepared to support them with this additional healthcare activity. As one patient stated, “It was really hard being diagnosed with cancer - it is really hard on you, but just as much on your family, so I didn’t want to burden them” (female, accepted).

Patients were also cognizant that their support persons needed to be able to coordinate the trial with their own schedules if they were going to help them participate. The following
prostate cancer patient described the support his wife provided him during his cancer treatment and how she negotiated time off from work in order to be with him at appointments. Similar logistical coordination would be necessary if she were to be involved in his participation in a CT:

   Yes she is. She takes notes, I don’t. I used to have the sort of mind where it wasn’t necessary to take notes, but now I have to take notes to make sure that I have tied both shoelaces, kind of thing. She is very helpful. She usually comes with me to appointments, but she is back at work now. She works in education, so it is great in the summer because she was off for two or three months and she was able to come with me every time I had to make an appointment. She will take time off work sometimes to sit with me through consultations. Yes, she is very much involved. (male, accepted).

   For some patients, the potential inconvenience of going to CT appointments was too burdensome because it would require over-relying on their social network. Social network could include a friend or community support (e.g., freemasons who offer drives) in addition to a spouse or family member. However, since friends and community resources were not family, some patients were very cognizant of not wanting to overuse them. The more friends patients had, the easier it was to spread out requests for assistance and to prolong their social support without overburdening them. One patient with breast cancer described how she “maxed out” her support network for attending treatments, which meant it was difficult for her to participate in a CT:

   Well, because I was often dependent on people to drive me places and I sort of maxed out the number of people I could have taking me here, there and everywhere. And this would have been even more appointments and then more arrangements to be made and more people to ask (female, declined).

Another patient talked specifically about the emotional burnout she and her family experienced after her cancer treatment. This patient declined the drug trial because they needed time to recoup:
You know, I did weigh the pros and cons and I felt bad afterwards that I'd made that decision, but my husband was like, ‘Honestly, from what you've been through, you really just need a break.’ And he did too. We all did (female, declined).

For many patients, the preservation of their relationships with family members was an important aspect of the decision-making process and reflects the core concept that no person is alone in making CT decisions. While some patients spoke of their family being supportive of whatever decision they made regarding CT participation, others were highly influenced by the wishes and beliefs of their family members. As previously mentioned, this was particularly the case for prostate cancer patients, many of whom went along with their spouses’ preferences related to CT involvement. A few female cancer patients also spoke of incorporating their family’s beliefs and values into their CT decision-making process. As shared by one patient with breast cancer:

It was just the sitting down and talking with family that made me realize that I wasn’t the only one involved in this decision and I wanted to make everybody happy. So my youngest daughter thinks, ‘No, I don’t want you to take any drugs that are experimental. You did do the chemo and the radiation…’ So I can understand that with her. So when I said that I would participate, I said, ‘I will participate, just as long as I’m not taking the drug, so put my name in the computer and if it comes out that I don’t take the drug, then I will participate, but if it is…’ and I did that just for my youngest child (female, accepted).

Preservation of important social roles was especially paramount for patients with small children, who described considering whether a trial might extend their life so that they could be there longer for their young children:

I had two small kids, it was mostly that I was going to do everything I could to get through this and to deal with the cancer so that I would be there for my kids and the relationships (female, accepted).

Some patients were prepared to experience short-term difficulties in their social relationships and responsibilities, such as being absent for work, in order to gain access to the best care and achieve long-term outcomes. However, this ultimately reflected patients’ concern for
their family relationships, since if they were parents, for example, their responsibilities were also to regain health so that their children would not be left on their own. According to one patient, the up-front logistical burden and emotional toll on her family was worth it as it gave her access to innovative therapy at a world-renowned institution that would potentially allow her to be there for her family in the long-term:

I live in [suburb], my care would have been in [suburb], I believe with having children that if my kids get sick I take them to children’s hospital. If I have cancer I don’t want to be in [suburb], I want to go, you know this is the place, [city cancer agency], you know where else would I go? So knowing that I was going to be treated here, because like again, because I live in [suburb], I know I could be in [suburb], it would take me ten minutes to get to the hospital there. I knew the travelling back and forth here was going to be a little more stress on me, but I would rather be here knowing that the care I was going to get here was bar-none the best. What other questions could you possibly…what other choices would you have? (female, accepted)

**Patient-oncologist relationship.** Patients’ relationships with their oncologists were also an important consideration in their CT decision-making process and reflected the larger import of social networks as identified in the “No Wo/Man is an Island” theoretical model. Most patients assessed what was at stake in the relationship and whether the trial was a study that their oncologist had a vested interest in or whether they were the lead investigator and under pressure to recruit. Some patients and families reflected on their previous treatment experiences with their oncologists and placed these physicians high up on a pedestal for treating their disease successfully. As a result, these patients and support persons described feeling indebted to the oncologist and were prepared to follow his or her recommendation about the trial because of their previous treatment history. As described by a support person:

Dr X is God to us right now, the way he gave us new life. It’s just right now we are not worried how long he’s going to live or something. At least we are not in the spell of waiting, you know, like one month is over now; two months is over (female spouse, supporting a patient with prostate cancer who accepted CT participation).
Another prostate cancer patient relayed an overt sense of dependency on his oncologist, reflecting how important his oncologist was to him; “so everything I asked him, he did. So that's the support I got and so it all revolves around him. If I lose him, it might be a tragedy” (male, accepted).

Although many patients felt dependent upon their oncologists for care, there was also a perception of a power relationship in the other direction, where patients recognized that oncologists needed their help to accrue to their trials. Many patients wanted to help their oncologists in their research programs as a way of returning the support that their oncologists had given them during their treatment. As shared by one woman with breast cancer; “The fact that Dr. X asked me and I feel like I’m giving back something to her research because I felt like she had been so supportive of me. So it was a reciprocal thing” (female, accepted). Patients appeared to perceive these situations positively as allowing them to regain a sense of control or balance the power differences between them and their oncologists.

Other patients talked about being grateful for the opportunity or for being “chosen for a trial” by their physician. One prostate cancer patient described how his desire to support his oncologist’s research overcame his concerns about the underlying motivations and credibility of the CT industry as a whole. There is a possibility, however, that this patient was misplacing his trust in his oncologist if his decision was also motivated by the belief that the CT would potentially benefit him as a form of treatment:

And we know that these trials are not perfect. I mean, we've done enough research, like especially on the American side with the FDA and the pharmaceutical industry, to know what the motivations are, where they lie. And so discounting that, though, I'd say that we still feel that it's an attitude of gratitude, you know, that we're chosen in something like this 'cause Dr. X and Dr. Y and those people put a lot of time and effort into this, heart and soul (male, accepted).
**Decision-Making Types**

The way in which patients engaged in the above processes appeared to be encompassed in two types of decision-making: *snap* or *reflective*. Relating back to the core construct, patients within each decision-making type differed according to which relationships and social networks were consulted and influenced their CT decisions.

The majority of snap decision-makers engaged in a streamlined decision-making process that relied heavily on establishing credibility of their oncologist and then faithfully following their oncologist’s recommendation. Thus, most snap decision-makers only minimally engaged in seeking further information and/or bypassed weighing pros and cons altogether because they perceived their oncologist had already done this on their behalf. The majority of these patients felt it was their oncologists’ job to know what would be beneficial for them. As discussed by a prostate cancer patient:

> I was very impressed with his [oncologist’s] knowledge and what he’s doing, and his research. And his bedside manner. And he has empathy for the condition that I’m in and I’m sure he has empathy for his other patients as well. So I trust him 100%. And so when they came out and said, you know, clinical trial, you’re good for a clinical trial, I said okay, well let’s go for it. But then found out later I wasn’t. So that’s what happened with the first clinical trial is I was ready to go simply because Dr. X had said that it was good for me. Or it would help me perhaps, but it wouldn’t hurt me. And so I was ready to go there (male, accepted).

Placing trust in the oncologist to make the best decision often meant not getting more information or patients limiting the questions they asked of their oncologists. As one breast cancer patient with a long-standing relationship with her care provider mused:

> He asked me…he just asked me if I was wanting to go in it [CT] again because I had been in one before and he was my oncologist then too. So he’s been looking after me for eight years pretty much, yeah. But I just pretty much put my whole situation in his hands because I didn’t really know what my choices were. But I certainly wasn’t against it (female, accepted).

Patients’ stage of disease also had bearing on whether they were more or less likely to
make a snap decision based on their oncologists’ recommendation. With time running out, advanced cancer patients believed it made sense to trust the doctor’s opinion and only minimally engaged in seeking information and weighing pros and cons. As shared by the following prostate cancer patient:

Well, I was running out of options so it was more by default. It wasn’t that I studied a hundred things and then chose this one. Dr. X, my urologist, we have a lot of confidence in him and he wanted to get me into this trial because – and I’d read a little bit about it before ’cause we had a clipping out of the paper. And Dr. X, he’s got a good reputation. So as I said, we read a little bit about him and then Dr. X suggested it to us, so he more or less bridged the credibility there. And that was it (male, accepted).

There were only a few participants in this study that made snap decisions to decline a trial, thereby making it difficult to fully describe the antecedents and process of a snap refusal of a CT. However, from the interviews it appears that snap decliners were influenced by their previous experiences with CTs or strong a priori beliefs about CTs. These experiences and beliefs provided them with very concrete ideas about what they would and would not accept as CT participants. For example, some patients were unwilling to risk the possibility of experiencing serious physical side effects or of receiving a placebo. As described by one patient with prostate cancer who made a snap refusal to participate in a CT after learning the trial would involve a placebo: “I said I would not be in a trial or in a situation where I had a placebo. I refused to participate if that were the case” (male, accepted).

Whereas snap decision-makers tended to make a quick CT decision based on select information or previous experience with trials, the majority of reflective patients engaged in weighing pros and cons. For these patients, the latter process often meant doing their own “due diligence,” which was important for them to feel satisfied and confident in their
decision-making. Many of these patients did not have rapidly progressing disease so there was not a sense of urgency to make a quick decision. They were also given the time to reflect upon CT information with their support persons. As another prostate cancer patient explained:

Well, like I said, I’m well-informed, otherwise I would not rush into my decision. I mean, that’s a very important decision. So in other words, I know exactly what I’m up to. They [CT personnel] give me a lot of time to think it over. It is never rushed. Otherwise I don’t participate. In other words they [the CT personnel] give me a lot of freedom, you know, to make my own decision. They present all the information and it is entirely up to me to read the information and digest it. And of course I also discuss it with all my members of my family and my family doctor (male, accepted).

Higher education (college and/or university level) also influenced patients into assuming a reflective decision-making type. These patients were better able to understand the CT information presented to them. Also, many reflective patients believed it was their responsibility to consider the trial from their perspective (rather than relying on the oncologist to make the decision for them). One patient with prostate cancer shared how his previous experience of making treatment decisions enabled trust in himself to make his own CT decisions:

Based on my own methodology of saying here’s how I’m gonna decide whether I’m gonna take the treatment or not take it. It’s just like I’ve been offered chemotheraerpy and I said I’m not doing it. You’re gonna die. Well, okay, I’m gonna die. Wel, I didn’t die and I didn’t take chemotherapy. So I’m pretty confident. I basically go on how I feel and I have a pretty good intuition now regarding my health after 16 ½ years of dealing with it (male, declined).

**Influencing Factors**

As previously identified, there were a broad range of influential factors that informed the decision-making phase of the “No Wo/Man is an Island” theoretical model. These factors included patients’ perceptions of illness severity, trial type, previous and current healthcare experience, and gender. These factors influenced what kinds of and how much information
was important to patients, to what extent trust and credibility was important, and how
patients weighed the pros and cons of CT participation. In addition, perceived illness severity
and trial type influenced how patients weighed the pros and cons through the mediating
concepts of risk tolerance and choice perception.

Influencing factors are discussed in the following sections in terms of the overall “No
Wo/Man is an Island” theoretical model. However, some of these factors (e.g., trial type) are
more personally located whereas others are more socially or structurally imbedded. This is
not a detriment to relational theorizing about autonomy in the context of CT decision making
because personal factors are still important to establishing a sense of ‘self’ recognized within
relational autonomy theory. The extent to which personal factors are influenced by social and
structural factors within the CT decision-making process will be identified in the following
sections, where appropriate.

**Perceptions of illness severity.** Perception of illness severity is a personal
influencing factor with relational implications. Patients who reported they had more
advanced disease were mostly concerned about their quality of life and whether the trial
intervention would work or the chances it would be helpful for them. These patients often
had a desire to live, which was influenced by their social roles and familial relationships.
These patients wanted to preserve their life in order to be present for important milestones
with their family or to be there for their children. As demonstrated by the following patient
with cancer who put his trust in his oncologist to enrol him in a CT: “I told him [the
oncologist] I wanted to celebrate my 90th birthday with my family. So implied in that was
that it’s up to him to make it happen” (male, accepted).
Families were also more encouraging of patients to make a decision that would prolong their life if the patient had advanced disease. Most advanced cancer patients and their families were prepared to consider CTs unless there were very severe side effects that would affect their remaining quality of life. This was often a family decision, as demonstrated by the use of “we” in the following quote from a patient’s spouse:

We don’t have any other choice. And then the history they told us, history, this medicine is in clinical trial…it’s the final leg a clinical trial, and is really working. And since he’s taking it and I obviously support him because when there’s a dead end and there’s little light in the tunnel, so you want to go for that light. So this medicine was just like light in a tunnel for us so we went for that. (female support person of prostate cancer patient, accepted, emphasis added).

On the other hand, patients with earlier stage of disease who had more treatment options available were concerned with catching a progression or recurrence of cancer. At this stage, families appeared more willing to allow their loved one to explore options since there was a perception of having time. Additionally, families often supported patients in choosing not to accept trial participation if other treatment options, with less potential risks, were available.

**Type of trial.** Trial type influenced how social networks were consulted and, in terms of the “No Wo/Man is and Island” theoretical model, who was invited onto the “island” to provide support and information to facilitate patients’ CT decision-making process.

There were two types of trials that patients discussed in this study: exercise and drug trials. Exercise trials were perceived as less risky and invasive; therefore, patients spent less time researching information about them and consulting their social network than drug trials. In addition, it was easier for patients to understand what these CTs involved because they worked on the “outside” of the body. This was different from drug trials, whose mechanisms were often perceived by patients to be clouded by mystique. Drug trials came with possible
harsh adverse effects, uncertainty about whether patients would receive the active agent or placebo and whether they would be effective. Because patients perceived drug trials as having greater implications for their health and safety, patients took them more seriously and either needed a strong indication from their oncologist that the trial was best for them (snap decision-makers) or spent more time researching information with the assistance of their social networks, establishing credibility and weighing pros and cons with their support persons (reflective decision-makers).

Type of trial influenced who was consulted about the decision because different types of information were required to address the different concerns. Patients wanted to know more about safety and efficacy of drug trials and so they reported consulting more with oncologists and CT personnel. In contrast, patients were more interested in learning about the logistics of exercise trials, and so they turned to support persons and peer groups, including other patients, to gain their perspectives on what kind of travel and commitment would be required.

**Healthcare experience.** Patients’ previous or on-going healthcare experiences had bearing on patients’ current CT decision-making process, and patients often reflected on the previous effects of trial participation (or not) on their families or relationships with health professionals. Often, patients with previous healthcare/cancer experience had already established rapport with the care team or credibility of the institution prior to being offered the trial option and, as a result, they were able to move quickly into assessing what their oncologist thought about the trial to inform their decision-making. Also, these patients may have had some familiarity with different treatments available to treat cancer or had an initial understanding of the trial process. Because of this, they had a level of comfort with the study information and were able to focus on gathering information with their support networks
about the particular experimental intervention rather than feeling overwhelmed with being diagnosed for the first time.

In weighing pros and cons, patients with previous healthcare experience often already had a sense of what was important to them because they had been through a trial before or they had experienced treatment for cancer. Some had very strong feelings that they would not do anything that had the potential for harsh side effects, because this might interfere with their social roles or quality of life, while others compared potential trial effects with the risks of standard therapy. Other patients who were currently undergoing cancer treatment or who had just completed cancer treatment were concerned about the logistics of getting to clinic appointments for a trial and also weighed the feelings of fatigue and burn-out on themselves and their loved ones, who would be supporting them if they were to participate in a trial. One support person, whose husband had expressed concern about her state of health if he decided to take part in a CT, described how she helped her husband through his cancer treatment:

I attend every single medical appointment with him. I’m there at the doctors taking notes. I usually go in with a list of questions, I take notes and then when we’re home if he’s not clear on something I’ll reiterate something. If there’s further appointments I’ve got everything organized in the day-timer. I do all the organizing. (female support person of prostate cancer patient, accepted)

Previous healthcare experiences related to the core concept in that patients reflected upon the impact a CT would have on their social network and spouses based on their past CT decisions. This influenced patients’ decision making going forward because they were aware similar support would be required from their social networks if they were to proceed with CT participation.

**Gender.** Both male and female cancer patients endeavoured to establish a trusting relationship with their oncologists and believed that their physician’s recommendation was
an important component of their decision-making process. Male patients, however, were more likely to be snap decision-makers, placing a greater amount of faith and trust in their oncologists’ knowledge and recommendations. Female cancer patients also sought to establish trust in their oncologist but, on the whole, tended to be more reflective in making their decision and were more externally focused on others’ needs. For example, women spent more time researching information and weighing pros and cons of the trial and the impact this could have on their family or young children. Some spouses of prostate cancer patients were described as pursuing a reflective decision-making pathway on behalf of their partners. These gender differences raise questions regarding how women and men approach healthcare decisions.

An intriguing difference between men and women that emerged from the interviews was the difficulty some female cancer patients had with focusing on themselves and making a CT decision based solely on what was best for their health or their clinical situation. These women were at times almost apologetic for thinking of themselves first and experienced guilt or shame for not living up to the image of iconic motherly caregivers, such as “Mother Theresa.” The women in the study were also more likely to express concern about “letting down” their oncologists if they chose not to participate in a trial or experienced guilt for not helping their oncologist accrue because they were exhausted from their previous treatments. Although most of the female cancer patients in this study were able to overcome these social pressures with support from their family or oncologist to ultimately make a decision that was best for them, it was not an easy decision without feelings of psychological dissonance and angst. These themes related to gender norms, and the influence of these norms on patients’
relational autonomy and social network will be more fully explored in the discussion chapter (see Chapter Six).

**Risk Tolerance and Choice Perception**

Perceptions of illness severity and trial type appeared to influence how patients weighed the pros and cons of CT participation through the mediating concepts of risk tolerance and choice perception. Patients were more or less tolerant of the uncertainty associated with the trial, depending on their perceived severity of illness. Patients with more advanced disease and their families demonstrated greater tolerance for uncertainty associated with the trial (i.e., whether or not they would receive the active agent, whether or not the agent would be effective for them) and minimized the risk of adverse effects because they had no other treatment options available. This brings up questions about patients’ vulnerability and families pressuring patients with advanced disease because of the limited remaining treatment options. One patient described how, if she had later stage disease, she would have imagined herself accepting greater risks in order to receive the potential benefits of trial participation:

> If my situation were different, and it might...as I go down the path, if this disease progresses, and my quality of life is different from now, then I might have a very different perspective going to trial. There might be a whole lot of different motivators that would... that I might be encouraged to take more risks (female, accepted).

Patients’ perceived severity of disease also related to the “No Wo/Man is and Island” theoretical model in that it influenced patients’ willingness to manage social and work responsibilities through the mediating effect of choice perception. Patients who reported more advanced disease perceived themselves to have fewer treatment choices left, which in turn appeared to make them more accepting of the burdens associated with CT participation. It also resulted in some patients, who were very sick and unable to actively direct their care,
allowing their families to be more involved in their CT decisions. The following patient accepted the burdensome logistics of CT participation, which would cause interference with his social and work roles, because there was no other alternative outside of the trial:

Well, I know it interferes with my work but there's nothin' I can do about it. When you're given this type of a choice, if you have to make adjustments, you make them (male, accepted).

Several advanced cancer patients and their family members did not feel they had a ‘real’ choice about participating in a trial – a trial provided them with a treatment option and the hope of survival. Refusing a CT left them with no alternatives beyond dying from cancer. In keeping with the relational nature of the model, spouses of patients who were faced with limited treatment options often described the CT decision-making process as a collaborative effort: “…when we went to the clinical trial, we didn’t have any other choice. [The] other choice, like if the doctor told him just for the one year he would live, and then…I get very emotional” (female spouse, male patient who accepted CT participation, emphasis added).

Trial type also influenced patients’ decision-making process through the mediator of risk perception. For some drug trials, one arm would involve standard treatment. Thus, patients described these CT decisions as easier to make because they perceived very little difference in risk between the trial and standard care. Other times, the standard treatment would continue no matter what decision they made. As explained by a breast cancer patient:

You’re going to get all the same drugs, and with this trial you get all the same drugs it’s just how they give it to you, why not. You can drop out any time, it’s not, it’s not going to be something that’s going to be harmful to you, you might as well take all the help you can get. See and I don’t know other people in other trials, maybe they’re getting drugs that are trial drugs right, I didn’t, I got the same drugs, just in different order or something (female, accepted).
CT Decisions

Characteristics of Trial Acceptors

Most patients who ultimately decided to accept trial participation were open to CTs prior to the trial offer. These patients believed in the value of research, either for the benefits to society or they recognized that the trial would give them the best treatment for their cancer, and so they were immediately more willing to consider CT participation. Several other patients were older and satisfied with their life so that they were ready to give back to science by volunteering for a trial. These patients were open to trials and valued being a “guinea pig” for the sake of scientific advancement.

Trial acceptors made either snap or reflective decisions to participate. The majority of snap decision-makers who accepted trial participation did so because they interpreted the trial offer as a physician recommendation for them to participate in order to get the best care. In contrast, reflective trial acceptors gathered more information and weighed the pros and cons. These patients value the benefits of participation more heavily than the downsides. They either downplayed the side effects of the drug or determined that the trial did not involve any greater adverse effects than what they would experience in standard therapy. They also considered the risks of the trial against their stage of disease (and mortality) and determined they had nothing to lose because more effective options to treat their cancer were unavailable. Coordinating travel to the study site was not an insurmountable challenge for patients who accepted trial participation. These patients typically lived close to the cancer agency or, if they lived far away, they determined the trial was too important to forgo because of logistical challenges. Supportive family and flexibility at work if they were not yet retired made it possible for these patients to travel to the study site and coordinate trial
appointments with their schedules. In contrast, patients who did not have supportive social networks and structural resources were sometimes precluded from participating in CTs, or at least experienced much more difficult in doing so.

**Characteristics of Trial Decliners**

Many patients who declined CT participation were closed to receiving CT information because of previous negative healthcare and/or CT experiences. Trial decliners were almost always reflective decision-makers, unless they were reportedly newly diagnosed cancer patients who declined trials because they were overwhelmed with their diagnosis (i.e., snap decision-makers).

The majority of patients who declined trial participation took seriously the potential adverse effects of the study and decided not to take the chance that they would experience significant physiological side effects. Decliners typically did not perceive their illness as advanced. They more often had other treatment options available to them, or their cancer was under control, and so they decided to stay with the “tried and true” course of therapy. Other decliners finished successful treatment for their cancer and needed a break from visiting the agency. These patients needed time for themselves and their families to recuperate. Still other patients who were seeking treatment for their cancer may have declined CT participation because they were unable to coordinate travel to the study site or they did not want to further burden their family or support networks to facilitate their participation.

**Trial Withdrawers**

Finally, some reflective patients who initially accepted a trial suggested they might return to the decision-making phase if their context changes. They indicated that if their social circumstances/life priorities changed, then they would need to gather more information
or re-weigh the potential benefits of the trial with the logistical demands or adverse effects.

As one patient who withdrew from a trial explained:

It [receiving follow-up and monitoring through a CT] was important to me until this year and, as I said, my last visit with her [oncologist] was approximately two weeks ago and she had indicated to me earlier on, a year or so ago, that because of the surgery, I no longer was concerned about breast cancer, per se, but if I wanted to have yearly checks with my own GP, that would be fine with her. And I sort of thought this year, as along with, as I said a minute ago, my feeling that I wanted to be just cancer free and that included not going to the clinic. That it was time to sort of cut my ties with [name of oncologist] and the clinic too (female, withdrew).

Both patients and CT personnel emphasized the opportunity to withdraw from a study as a facilitator of patients’ decision-making process. CT personnel believed they were taking away some patients’ fears of making the “wrong” decision, while many patients described the possibility of withdrawal as allaying their fears about experiencing adverse effects. Many patients believed that they would be asked to stop taking a study drug if it was causing them serious physiological side effects.

A few cancer patients imagined what it would realistically take for them to withdraw from a study if it was something that they initiated themselves. One patient worried that she would feel guilty about removing her data from the study because it might compromise her oncologist’s research. This woman demonstrated an awareness of the relational implications of trials, and perhaps felt a sense of indebtedness towards her oncologist that resulted in her not wanting her withdrawal from the study to negatively affect her oncologist’s research.

Another prostate cancer patient recognized himself as stubborn and thought he would not take the opportunity to leave a trial because he does not like change:

...give it a try because you can come off it if you want, or they might take you off it if it’s not doing well. But if it’s doing well, they leave you on it and if, for any reason you want to come off it, you’re allowed. But I wouldn’t do that; I don’t like too much change anyway. I think that’s... what do you call it - Capricorn - stubborn (male, accepted).
These additional patient insights demonstrate that the decision to withdraw is not always easy to make nor is complete withdrawal from a study always possible. Therefore, oncologists need to be aware of these relational influences when they attempt to promote patients’ confidence in their current decision-making process by reminding patients that they may withdraw from a study if they decide they no longer wish to participate. Instead of making the decision easier, delaying withdrawal may just postpone the difficulty of this decision or move it to a time when additional pressures and influences come to bear. For example, patients who have spent time in a trial may feel more indebted or invested in the oncologist’s research so that withdrawal from the study is even more of a challenge.

**Recommendations**

The recommendations presented in this section are based on my analysis of patients’ responses to what would have been helpful for their CT decision making. Most patients suggested more readily available information about trials would be helpful so that they are more aware of what options are available. This may be particularly useful for patients who are living far from the study site and who need to be proactive in gaining access to trials because of perceptions by CT personnel that they may not have the means or willingness to travel. By increasing the accessibility of CT information to all patients, some of the justice or structural issues related to CTs, and that impact patients’ relational autonomy, would be addressed (i.e., educated patients with social and economic resources having the means to research trials and advocate for themselves in order to gain access to trials).

Patients also discussed how information could be timed better so that the CT option is not provided at the point of a cancer diagnosis or when patients are overwhelmed with their treatment. Finding the right time to discuss trials with patients is an important social and
structural precondition for patients’ ability to understand what is communicated to them. However, patients acknowledged that figuring out the best time to approach them is a difficult task and that oncologists’ time is restricted by a lack of structural resources to support trial discussions. As well, some trials need to occur at a specific time post-diagnosis, so oncologists do not have much choice about when to offer them.

When considering information provided in the consent form, some patients appreciated that every single possible adverse effect was listed. However, others became overwhelmed with all the side effects and very fearful of some of the more serious ones, despite their low probability. In the interviews, only a few patients were able to situate the adverse effects in the context of other healthcare interventions in order to control their fear. For example, several patients believed that over the counter medications, like aspirin, have some very serious side effects but there is a very low chance of actually experiencing them. Acknowledging the emotional aspects of patients’ experience of cancer within the patient-oncologist relationship is important so that irrational fear may be addressed. Furthermore, structural changes related to what type and how much information is conveyed in consent forms would be helpful.

Conclusion

The “No Wo/Man is an Island” theoretical model of patients’ decision-making process has identified several findings that are important for the advancement of this field of research.

One finding, that has not been sufficiently explored in previous research to date, is how most patients arrived at the CT offer phase already open or closed to learning about CTs based upon their predisposing factors. Patients’ initial conceptions had implications for
whether and to what extent they were receptive to full and complete information about trials. Typically, many patients were inclined to gather specific information to further support their initial perspective, which was informed by social and cultural considerations of CTs or previous healthcare experiences. This particular finding has implications for how best to support cancer patients’ understanding for relationally autonomous CT decision making and informed consent. Although research has shown promising results in the use of communication aids to support the transfer of information during the oncologist/researcher-patient consult (Hack, Pickles, Bultz et al. 2003; Hack, Hack, Pickles, Bultz et al. 2007), this study suggests that targeting patients prior to receiving a trial offer may prove to be most effective, since this is when patients develop their level of receptivity to trials. For example, advertising trials in order to raise social awareness and knowledge about CTs may be a promising strategy.

The findings from this study also identified framing of the trial by oncologists, as well as their non-verbal cues, as important influences on cancer patients’ decision-making process. Previous research has so far been inconclusive as to the extent to which framing impacts patients’ trial entry preferences. Some studies have found it to be significant (Edwards, Elwyn, Covey, Matthews, & Pill 2001; Siminoff & Fetting 1989) while other studies have found no significant relationship between framing and trial entry preferences (Llewellyn-Thomas, McGreal & Thiel 1995). The current study supports renewed efforts to understand when framing is influential and how it can best be managed in order to preserve patients’ relational autonomy within the decision-making process. Practically, oncologists may need further education about trial presentation and their potential impact on patients.
The findings from this study contribute a more nuanced understanding of decision-making approaches and highlight the role of trust and patients’ perception of time on the type of approach that they utilized. Shortly after receiving information about a trial, patients either proceeded to make “snap” or “reflective” decisions about whether to participate or not. These decision-making types existed on a spectrum, with only a few patients making snap decisions to accept a CT by placing their decision-making authority completely in the hands of their oncologist. Other snap and reflective decision-makers assumed some authority and were more proactive in their decision-making process to various degrees.

Previous research has sought to understand this issue in terms of the degree of control patients prefer in making decisions (Hack, Degner & Dyck 1994). According to some researchers, patients who prefer to cede decision-making authority to physicians are considered passive in their approach, whereas patients who want to share or make the decision with input from their physician are more collaborative or active decision-makers (Degner and Sloan 1992; Cassileth, Zupkis, Sutton-Smith & March 1980). However, this study suggests a revisiting of these categories since being “passive” in the CT decision-making process may actually reflect patients who have actively decided to conserve their energy or who have acknowledged the oncologist as having the knowledge and expertise to make the best decision.

Snap decision-makers’ assumptions that oncologists are considering their best interests in recommending a trial are built on the fiduciary nature of the doctor-patient relationship. However, different norms apply in the oncologist / researcher-patient relationship (Levine 1992). In these cases, trust may be misplaced because the patient assumes the beneficent concern as part of the role of the physician applies equally to the role
of the researcher (McDonald, Townsend, Cox, Paterson, & Lafrenière 2008). Furthermore, as shared decision-making becomes the gold standard approach, where patients and physicians make decisions together (Charles, Gafni, & Whelan 1997), findings from this study support the inclusion of a spouse or family member in this decision, so that sharing is acknowledged to not only occur between two people (oncologist and patient), but is a tripartite (or greater) approach to decision making. For example, the influential role of social networks in facilitating patients’ access to trials is a significant part of patients’ weighing the pros and cons process. Social networks are crucial for assisting patients in determining whether they have the time, energy, and ability to take part in CTs, since social networks help patients attend appointments and provide emotional support. It is important for patients to be able to coordinate study appointments into their schedules, but it is almost equally important that families, spouses, or support persons are also able to coordinate the trial with their schedules. Greater attention to ways to involve support persons in order to remove barriers to CTs and facilitate cancer patients’ decision-making process is required. On the other hand, these findings may also suggest the provision of more practical supports to patients so that they are not so reliant on their social network.

The model highlights aspects of cancer patients’ decision-making process that may be suboptimal according to some standards. Psychology literature (Janis and Mann 1977), and more recently neuroscience (DeMartino, Kumaran, Seymour, & Dolan 2006) has recognized that actual decision making typically falls short of the rational, informed and free from emotion exercise that is heralded by traditional autonomy theorists. For example, frames, emotions and biases often come into play, and sometimes for very good reasons, such as there may not be enough time to carefully consider all the options or as a way to deal with
uncertainty (Tversky & Kahneman 1975; Hastie & Dawes 2009). A particular decision heuristic used by cancer patients in our study may be best understood as the confirmation bias, where patients gathered information that affirmed their initial conceptions. Furthermore, the role of patients’ emotions, such as their fear of adverse effects or hope for a cure, also had an influence on patients’ decision-making process. The latter could inform an optimistic bias that might cloud patients’ understanding of the actual risk and benefit ratio. CT personnel need to support patients in overcoming potential biases so that all the relevant evidence is taken into account in the final decision.

Finally, the issue of uncertainty was significant for the majority of patients. Participants described two different ways of managing their uncertainty, staying with the tried and true therapy, which resulted in declining a trial, or perceiving nothing to lose, which resulted in trial acceptance. Few studies have explicitly examined uncertainty associated with cancer patient decision-making about CT participation even though this is a significant characteristic of their decision-making process, given that trials by their very nature involve experimental interventions about which much is still unknown, and there is an uncertain potential of receiving a placebo treatment.

In summary, this study provides a new model for understanding cancer patients’ decision-making process within the context of CTs, including behavioural interventions. The “No Wo/Man is an Island” theoretical model identified several key phases of patients’ CT decision-making process. Also, and in keeping with relational autonomy theory, the model identified the significant role of social networks and structural influences on this process. Patients relied on their spouse, extended family, peer support groups, GPs, and oncologists to support them throughout all phases of the model. Even when patients said they made CT
decisions independently, in the following breath they acknowledged the central role of their spouses or families in how “we” made decisions “together.” Structural influences such as lack of CT resources to conduct trials and gatekeeping behaviour related to patients’ socioeconomic position and geography also influenced patients’ CT decisions. Power relationships between patients and physicians, as well as the emotional state of cancer patients, further influenced patients’ CT decision-making process. Therefore, this model illustrates that no cancer patient made CT decisions completely free from social and political influences, such as power differences within the patient-oncologist relationship and social inequities. No cancer patient is simply an individual “island” in his or her CT decision-making proces.
Chapter Six: Discussion

In this chapter, the empirical findings of the previous two chapters are situated more broadly in relation to the current literature and theoretical lens of relational autonomy. First, relational autonomy theory is used to further explore and critique the empirical findings, including identifying which influencing factors are supportive of cancer patients’ autonomy during the clinical trial (CT) decision-making process, which are undermining, and why this is the case. A critical feminist lens is used to elucidate the impact of power and gender on patients’ decision-making processes and relational autonomy. Next, practice recommendations are proposed based on the themes identified that will support cancer patients’ relational autonomy within the CT decision-making process. Finally, the limitations of this research are considered and future research is proposed to advance the field.

Relational Autonomy Analysis of Cancer Patients’ Decision-Making Process About Clinical Trials

Revisiting Relational Autonomy Theory

As explained in Chapter Two, relational autonomy calls attention to the social and structural conditions underlying persons’ enactment of autonomy, with particular examination of how relationships of power mediate the development and exercise of capacities for autonomy. The following discussion will touch on the overlapping personal, social and structural factors that were identified in participant interviews that warrant further attention and consideration in the context of supporting cancer patients’ relational autonomy within their CT decision-making process. Key themes discussed include: issues of justice and equitable access to CTs; therapeutic misconception and the dual role of the oncologist-investigator; and the social influence of family members and CT personnel. Finally, issues
related to gender in the context of patients’ CT decision-making process that may place undue pressure on their relational autonomy are explored.

**Theme A: Justice and Equitable Access**

The extent to which trials are available to all patients, regardless of their socioeconomic status, mental health or geographical location, is a justice and equity consideration that has implications for patients’ relational autonomy. The concepts of justice and equity in research ethics means that particular groups should not bear an unfair share of direct burdens of research participation nor should they be unfairly excluded from the potential benefits of research participation (CIHR 2010). Equity issues arise and have implications for justice when some populations are inappropriately excluded from research participation on the basis of certain attributes. In this research, study findings revealed that oncologists’ pre-screening practices during the CT offer phase – notably various forms of gatekeeping – were inappropriate barriers to some cancer patients’ accessing CTs. In the following, the justice implications of gatekeeping are discussed.

**Gatekeeping.** Pre-screening is necessary to ensure only appropriate patients—those that meet the eligibility criteria within the trial protocol—are involved in CTs. Gatekeeping is defined as the process by which healthcare providers prevent eligible patients from accessing research studies (Sharkey *et al.* 2010).

Our findings indicated that some oncologists engaged in gatekeeping; screening patients based on reasons outside of the defined eligibility criteria. Patients were systematically excluded for overlapping social and structural reasons, including the absence of social supports, lower socioeconomic status, rural housing, or a history of mental health or addictions issues. It is unclear from the data whether oncologists were being intentionally
discriminatory – many spoke about the emotional and physical capacity of patients to engage in complex trial protocols and were concerned about not overburdening them. Their attempts to protect patients they perceived as lacking the resources needed to participate in CTs, however, could ultimately be damaging to patients’ relational autonomy in several ways.

First, the restriction of access to CTs selectively denies some patients potentially meaningful options for choice, thus limiting their opportunity for autonomy by “prematurely excluding options the patient might have preferred” (Sherwin 1998 p. 26). This was demonstrated in an interview with a female patient who had advanced cancer and who reported being upset that her oncologist did not offer her a trial based upon assumptions about her financial situation and ability to travel.17 This patient explained how the trial option was important to her because she perceived it as her last opportunity to receive potentially curative treatment before palliative care (see Chapter Five).

Second, lost opportunities for choice also constitute lost opportunities for patients to develop or refine their autonomous capacities. By not offering the option of a CT to qualifying patients (e.g., those who meet “physiological” eligibility criteria for the trial, as identified by CT personnel in Chapter Four), patients are denied the opportunity to both reflect upon their interests in relation to trial participation, and make a choice that is aligned with their values and preferences. Groups of patients who are already vulnerable are robbed of essential opportunities to understand themselves as autonomous persons, and this may

17 The patient’s assumption was that the oncologist made the decision not to offer her the CT based on geography and ability to pay. No other assumptions were made, such as the patient would have a poor chance at benefitting from the CT. Since the patient had advanced cancer with the next step being palliative care, the trial – even if it offered a very small chance of benefit – was a risk the patient was willing to take.
make it more difficult for them to develop or recover their capacities. For example, patients with mental health or addictions issues may also experience poverty and have an eroded sense of self-respect prior to their encounter with the cancer care system (Kearney 1998). Self-respect is crucial for maintaining patients’ sense of themselves as being capable of making independent judgments (Sherwin 1998; McLeod & Sherwin 2000). These additional challenges may make it more difficult for certain patients to overcome oppression and build their autonomy capacities. The marginalization of these patients through gatekeeping does not address the fundamental social inequalities at the root of these issues. The result is that issues of justice are worsened because certain populations are not involved in CT decision making and they do not have the opportunity to develop or refine their skills for autonomy in this context.

Finally, various constraints result in what might be called ‘structural gatekeeping’. Structural gatekeeping occurs when patients’ opportunities for trial participation are limited by systemic factors built into clinical trial infrastructure. One example is the increasingly complex nature of oncology trials. Trial complexity can bias recruitment toward patients who are well educated and better able to understand complex consent forms. The growing scarcity of funds for CTs in Canada (Canadian Cancer Research Alliance 2011) is another important factor. This lack of funds has resulted in trials being located in urban settings and has restricted the resources and personnel available to support wider recruitment across populations that may require more support and economic resources to participate. As a consequence, trial enrolment is increasingly biased towards patients who have economic

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18 This concept was developed by the researcher to account for structural, rather than social (oncologist) influence on patients’ access to CTs.
resources, and are situated within an urban setting. This raises equity issues regarding the exclusion of select groups and is undermining these patients’ relational autonomy insofar as they are not provided the option of CTs. Lastly, extensive eligibility criteria, typically physiological or functional status and age criteria, are systemic barriers when they unreasonably limit CTs to a select subset of patients that do not correspond to the average patient.

Gatekeeping also has broader social justice implications that may undermine relational autonomy. Insofar as those excluded by gatekeeping include members of already vulnerable and/or marginalized groups, these practices reinforce rather than redress extant inequity by creating a body of knowledge that is not generalizable to all members of society. For example, those disadvantaged by poverty, lower education, or a minority ethnicity typically have higher cancer incidence and poorer cancer-treatment related outcomes (American Cancer Society 2013). With these patient groups being more likely to be excluded from cancer research, they will thus be subject to treatment that is based on research grounded in other patient groups’ experiences. As a consequence, these patients are even less likely to receive high quality cancer care that recognizes their unique context.

The significance of this problem has been explored in detail by W.A. Rogers. Rogers notes that the context of clinical application may differ substantially from the controlled context of a trial setting (Rogers 2004). For example, the physiological make-up of various cancer patients may differ across diverse populations. Those with mental health and addictions may have unique biochemistry that interacts with cancer drugs differently than
patients from other groups. Indeed, the emerging era of “personalized medicine”\(^\text{19}\) recognizes important differences in patients and seeks to develop more targeted and individualized therapies as a result. Instead of the scientific method viewing all subjects as homogenous to ensure the generalizability of the findings (Baylis, Downie & Sherwin 2000), personalized medicine is premised on heterogeneity, where knowledge about individuals’ molecular and clinical profile is key to developing more focused therapies and pharmacogenomics to improve healthcare (Ginsberg & McCarthy 2001).

Without trials that establish the efficacy and effectiveness of drugs that are relevant to all populations stricken with cancer, evidence-based cancer care and policy decisions will not be applicable to these populations. Certain groups may then be subjected to novel risks that could not have been foreseen because they were excluded from the overall research agenda. Cancer patients who have higher income and live in urban centres already fare better in terms of cancer survival outcomes and quality of life (American Cancer Society 2013). Gatekeeping during the recruitment process will perpetuate inequalities in survival and quality of life by continuing to deny CTs to already disadvantaged groups and by not examining the efficacy, effectiveness and safety of treatments in these populations.

In sum, gatekeeping has the potential to limit some cancer patients’ relational autonomy at multiple levels. It illegitimately restricts some patients’ opportunities for meaningful choice concerning trial participation. Gatekeeping also further entrenches existing social inequities by excluding certain groups from practice innovation. Insufficient and inappropriate healthcare, similar to other structural injustices (e.g., inequitable

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\(^{19}\) The term “personalized medicine” was first described in the field of genetics, and refers to knowledge of individual genetic variability in drug response (see Shastry 2006).
educational opportunities and economic resources), can impede patients’ autonomy at a fundamental level, since without good health and other material conditions, the range of options available for persons to pursue life projects will be limited (Sherwin 1998).

**Theme B. Therapeutic Misconception**

As mentioned in Chapter Four, the therapeutic misconception occurs when “a research subject fails to appreciate the distinction between the imperatives of clinical research and of ordinary treatment, and therefore inaccurately attributes therapeutic intent to research procedures” (Lidz & Appelbaum 2002). The current study findings revealed that both cancer patients and CT personnel suffered from therapeutic misconceptions regarding CTs. In the following, the concept of therapeutic misconception is further clarified, and the social and structural factors contributing to it in this context are identified.

**Clarifying the therapeutic misconception.** Since the therapeutic misconception was first described by Appelbaum in the 1980s, its definition has been the subject of significant debate (Henderson et al. 2007). Horng and Grady (2003) distinguish three types of misunderstanding in the research context: therapeutic misconception, mis-estimation, and optimism. Whereas therapeutic misconception refers to mistaken assumptions about the personal meaning of trial participation, therapeutic mis-estimation refers to patients’ misunderstanding of the risk/benefit probabilities of a trial. Therapeutic optimism refers to patients’ hope that the trial might benefit them (Horng & Grady 2003).

Of the three, Horng and Grady argue that only the first – therapeutic misconception – always undermines patients’ autonomy because understanding the nature of the research is necessary for autonomy and informed consent. According to Horng and Grady, therapeutic mis-estimation and optimism are not necessarily problematic. In their view, as long as
patients are simply interpreting the facts in their favour, this has little negative impact on meaningful decision-making. Indeed, positive interpretation of this kind may reflect a hopeful attitude that is conducive to healing and does not by itself constitute an affront to autonomous decision-making (Horng & Grady 2003). More recent work has sought to distinguish hopefulness as a dispositional trait from unrealistic hope or optimism that causes bias or distortion in understanding (Jansen, Appelbaum, & Klein 2011).²⁰

This research supports the importance of distinguishing between therapeutic misconception, mis-estimation, and optimism as patients and personnel exhibited distinct understandings of trial participation. For instance, several cancer patients with late stage disease and limited treatment options optimistically interpreted uncertainty about the outcomes of an experimental intervention as having the potential to help them (therapeutic optimism).²¹ This optimism appeared to increase these patients’ willingness to accept greater risk for the possibility of benefit without distorting their understanding of the trial as a whole. They were able to describe the purpose of research as distinct from treatment and that the primary aim was to discover whether the intervention was effective.

In contrast, some patients with advanced cancer were perceived by CT personnel as being desperate to participate in a trial because it provided them with a final treatment option. These patients appeared extremely anxious and hoped a trial would benefit them because they had already tried standard treatment with no success. However, these patients appeared

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²⁰ Future research is needed to consider how unrealistic hope impacts patients’ CT decision-making process, as well as the patient-oncologist relationship, including perceptions of trust within this relationship.

²¹ This was the case even when oncologists-researchers explained the risks.
to exhibit therapeutic misconception that undermined their relational autonomy because their distress clouded their judgment and understanding about the purpose of trials.

Indeed, this research supports an additional distinction. Some patients in the grounded theory study who declined a CT offer were more likely to overestimate the risks rather than the benefits of research, preferring to stay with the “tried and true” course of therapy. Other patients held strong negative beliefs about being a guinea pig that informed their decision to decline a CT offer. These patients might be suffering from what has been called the “injurious misconception”, which is an overstating sense of risk or threat that some authors have identified as the flipside of the therapeutic misconception (Snowden et al. 2007).

Before ascribing misconceptions, mis-estimations, or misguided optimism to patients, however, it is important to determine whether patients’ beliefs about CT participation result from a failure of individual cognitive ability, or, are conditioned by the social and structural context in which CTs are conducted. A relational autonomy lens is ideally suited to answer this question.

Relational autonomy and the dual role of oncologists. The dual role of oncologists as both care providers and study investigators is a noteworthy feature of the social context of most CTs, where oncologists have care relationships with patients that extend well beyond CT recruitment. In general, when oncologists are practicing medicine, they are performing activities designed to enhance the wellbeing of the individual patient. When oncologists are acting as researchers, however, their primary interest is in benefitting future populations (Levine 1992). This dual role may undermine patients’ understanding by creating confusion about the purpose of CTs and encouraging patients’ misconceptions – therapeutic and otherwise.
Misconceptions may be propagated in various ways. For example, patients in this study were almost always notified about CTs by treating oncologists, who were also either involved as a principal investigator or collaborator in the trial being offered. As a possible consequence, many of the cancer patients interpreted the trial offer as a recommendation from their oncologist to participate in a CT because they thought it would be beneficial for them as a treatment.

There is also evidence that oncologists, nurses and other health professionals suffer from the therapeutic misconception and, as a consequence, fail to communicate the purpose of a CT effectively (King 2000). This was substantiated by interviews with CT personnel, in which some oncologists stated they were first concerned about their patients’ treatment or health when making a trial offer (see Chapter Four). Other studies suggest that oncologists view CT participation as the best therapeutic option for some of their patients and, in many cases, the only way to access novel treatment (Joffe et al. 2001).

In our study, there was also frequent slippage between “trial” and “treatment” in CT discussions, suggesting that CT personnel do not clearly distinguish research from practice. In another empirical study, 46% of healthcare providers (i.e., nurses and physicians) believed the main reason for CTs were to provide therapeutic benefits to future patients (Joffe, Cook, Cleary et al. 2001; Miller & Rothstein 2003). Thus, patients’ discussions with oncologists about CTs may result in therapeutic misconceptions about trial participation because oncologists themselves suffer from therapeutic misconceptions about the goals of research.

**Structural influences surrounding the therapeutic misconception.** The CT context is also characterized by various structural conditions conducive to therapeutic misconception. Despite ethical guidelines that emphasize the distinction between practice and research
(CIHR 2010; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979; World Medical Association 1964, 1975, 1983, 1989, 1996, 2000, 2002, 2004, 2008), cancer research and treatment are often intertwined at micro, meso, and even macro levels. At the macro level, for example, the official position of the Oncology Nurses Society (ONS) in the U.S. is that CTs represent a component of essential services aimed at reducing cancer risk, morbidity, and mortality. According to ONS, all cancer patients should have the opportunity to participate in CTs as part of comprehensive cancer care (Oncology Nursing Society 2012). Similar views are embedded in the Canadian oncology community. For instance, as part of a national strategy to increase cancer research in Canada, it has been argued that each Canadian living with cancer should be offered a trial as a “standard” treatment option (Cancer Advocacy Coalition of Canada 2012).

The confounding of research and treatment has long been standard practice in pediatric oncology where it is common to present all trial phases that involve new drugs or interventions as treatment. The Children’s Oncology Group (COG), a cooperative clinical trials group comprised of 200 participating hospitals explicitly promotes the integration of trials into standard practice for children, adolescents, and young adults (Children’s Oncology Group 2013). COG divides trials into therapeutic and non-therapeutic depending upon whether the trial will “provide a specific treatment.” According to COG, Phase I-III trials are all therapeutic because they are used to evaluate “new treatments.” By blurring the lines between research and therapy at the policy level, organizations like COG create structural conditions that reify the therapeutic misconception. These structural conditions, in turn, may propagate therapeutic misconceptions on the part of patients and providers.
There is evidence that consent forms, a central structural feature of research involving human subjects, also perpetuate therapeutic misconceptions. For example, Kimmelman and Palmour (2005) conducted a content analysis of the consent forms used in Phase I gene transfer studies. The authors assessed how often the benefits and risks of trial participation are presented in optimistic versus cautious terms. Despite the fact that Phase I gene transfer studies are experimental and extremely unlikely to provide direct benefit to participants, the authors found that information was often inappropriately optimistic, used therapeutic terminology, and emphasized direct benefit to participants (Kimmelman & Palmour 2005). Clearly, statements in consent forms that inaccurately promote direct benefit or “treatment-oriented” outcomes may encourage patients to view a trial as therapeutic (King 2000).  

While therapeutic misconceptions do constitute a real threat to informed consent and relational autonomy, it is important to emphasize that therapeutic expectations related to trial participation are not always evidence of therapeutic misconception. According to some authors, when experimental interventions are offered with “therapeutic warrant,” trial participants may justifiably expect therapeutic benefits (Anderson & Kimmelman 2010). Arguably, the experimental interventions under study in late phase cancer studies (Phase III and some Phase II trials) are offered to participants with therapeutic warrant obtained from...

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22 Further research is required to understand whether such consent forms take advantage of patients’ trust in their physicians, and ultimately are damaging to the trust between patients and physicians, when benefits fail to be realized.

23 Therapeutic warrant means that the intervention is supported by evidence “sufficient to justify a belief that it may present research subjects with a favourable balance of risks to to direct benefits” (Anderson & Kimmelman 2010, p. 80).
earlier phase studies (Phase I and some Phase II studies). The cancer patients interviewed in the current study were offered participation in Phase II and III trials, thus there is a possibility that their therapeutic expectations were justified.24

When the therapy in question is already approved elsewhere in Canada, patients’ therapeutic expectations concerning participation may well be justified. In these cases, CT participation is often the only way to access therapies that might otherwise be locally unavailable. Despite having a socialized healthcare system in Canada, there are discrepancies across the country regarding the availability of new pharmaceutical drugs and therapies. Each province is in charge of its own healthcare spending and has its own drug review process. As such, a drug may be approved and available in one province but not in another (for a larger discussion see O’Reilly & Venkatesh 2010). CTs, therefore, may be the only way for patients to access a particular therapy in their province of residence.25

Finally, participants may hold legitimate expectations concerning the ancillary benefits of trial participation. Easter, Henderson, Davis, Churchill, and King (2006) described how patient care is often more comprehensive in the context of a research study because healthcare providers have the time and resources to give personalized support and

24 CT personnel need to be aware of how they present trials if there is a question about whether patients are able to psychologically separate therapeutic optimism from therapeutic misconception.

25 The inconsistency in cancer drug review and approval is being tackled by a pan-Canadian Oncology Drug Review body. The mandate of this body is to promote interprovincial collaboration to conduct clinical and economic reviews of cancer drugs and to provide recommendations about funding to the participating provinces (all provinces except Quebec) (Cancer Advocacy Coalition 2012, p. 15). This will allow for better alignment of cancer drug coverage across the country and timely decision-making about funding, which will impact how patients gain access to drugs, whether through CTs or standard care.
develop close relationships with participants. Participants in the current study shared this view. The extensive follow-up and monitoring associated with CTs, and the presence of a study nurse to assist patients navigate the cancer care system, were found to be highly valued by patients in our study. By contrast, both patients and CT personnel commented on the absence of “tender-loving-care (TLC)” or humanity in the current system due to fiscal constraints and the erosion of cancer treatment resources (Canadian Cancer Society 2013). The Canadian healthcare system, as a whole, has been criticized for being a fragmented “maze” of tests, appointments, treatments, and services (Canadian Partnership Against Cancer 2010). These structural conditions jeopardize patients’ relational autonomy as the opportunities available for meaningful choice are severely constrained, with CT participation often being perceived by patients as the only way to obtain quality cancer care.  

In sum, the social and structural conditions characteristic of the cancer care and CT systems (e.g., policy, trial design, consent forms, access to related resources) make it difficult for many patients to resist viewing CTs in therapeutic terms. Indeed, some CTs do appear to offer the most effective treatment available because the drugs have already been approved elsewhere or the particular trial has therapeutic warrant. When trial enrolment becomes the

26 A relational autonomy view would argue that the healthcare system could be doing more to assist patients and families (Sherwin 1998). Programs, such as patient navigation, are currently being examined as a way to provide a variety of support (e.g., informational, psychological, emotional, spiritual, physical, social and practical support) to patients and families (Canadian Partnership Against Cancer 2010). Until supportive care is standardized, however, patients’ relational autonomy is under threat. Without equitable access across the country to comprehensive cancer services, some cancer patients will be inclined to consider trials to meet their most fundamental supportive care needs.
only means of access to appropriate care and support, however, justice concerns emerge that may constrain cancer patients’ relational autonomy.

**Theme C. Social Influence**

As demonstrated in our findings, the role of patients’ relationships with oncologists, family, and friends, were highly influential across all phases of patients’ CT decision-making processes. Social networks not only informed patients’ predisposing beliefs and values prior to the trial offer, but they often provided support and encouragement for patients exercising their various skills and strategies associated with relational autonomy. For example, social networks helped patients access information and evaluate the credibility and trustworthiness of the institution and oncologist. Also, for many patients, social networks helped them weigh the pros and cons of CT participation. The following sections specifically examine aspects of the patient-oncologist and family relationships on cancer patients’ CT decision-making process in order to ascertain whether or to what extent these relationships undermined or enhanced patients’ relational autonomy.

**Patient-oncologist relationship.** According to interviews with patients and CT personnel, the majority of patients were influenced by what their oncologist thought about a trial. During the CT offer, patients were attuned to the way oncologists framed the trial, how much they emphasized the risks/benefits, their body language and tone of voice. Patients’ level of receptivity to trial offers (e.g., whether they were open or closed to learning about CTs) also oriented patients to information provided by their oncologist that would support their predisposing beliefs.

Kukla (2007) argues that physicians can enhance patients’ autonomy when they are knowledgeable collaborators in patients’ information seeking and other activities related to
decision making. They do this, in part, by nurturing patients’ investigational skills and judgment rather than merely informing them of the facts (Kukla 2007). This was demonstrated in some of the interviews with patients and oncologists. For example, one patient with prostate cancer described how his oncologist drew a diagram of the mechanism of the investigational drug to help him understand the underlying purpose of the trial. This tactic served to engage the patient in a format that was accessible to him and developed his competence in understanding the mechanism of drug reaction. Other patients reported asking their oncologist to describe or elaborate on probabilities of outcomes in ways that made interpreting this information easier for them. Few patients wanted to hear about risk and potential benefit from just a statistical perspective. Most preferred the oncologist to relate the risk of CTs against risks present in everyday life.

Some CT personnel identified challenges they faced when discussing risks/benefits with patients. Oncologists wanted to provide full information so patients could make an informed choice but they also reported sheltering patients from potentially distressing information to avoid “scaring” patients and causing them further harm. Whether or not disclosing this information undermines or supports patients’ autonomy in the context of CTs may depend on the individual situation. For example, forcing information on patients who do not feel prepared to cope with that knowledge could possibly undermine their autonomy by causing them further distress. However, sheltering patients could encourage a distorted sense of risk and undermine their ability to make a fully informed and autonomous CT decision. Full disclosure of the potential risks and benefits of a trial may allow some patients to

27 This would enhance the autonomy of those cancer patients who are already inclined towards CTs.

28 For example, the risk of crossing the street and getting hit by a bus.
consider different aspects of a trial and promote their ability to deliberate effectively about a trial. This was demonstrated in our findings where one patient explained that he would have thought further about a trial if he had known that it could cause him to be “sick as a dog” (see Chapter Five). In contrast, other patients were satisfied with not knowing and were more trusting of their oncologist. Some of these patients, however, may have been satisfied with their current level of knowledge because they were overwhelmed with their cancer diagnosis and could not accept additional information at that time. In this latter situation, oncologists should consider referring these patients to psychosocial support programs rather than failing in their duty to fully disclose the risks and benefits of a CT. On the other hand, perhaps some trials should be considered inappropriate for those patients who struggle to live with the uncertainty associated with CTs. Scheduling regular check-ins with patients about their participation in CTs or gaining consent again once a patient is enrolled in a trial are strategies that may ensure patients have not changed their minds about taking part in CTs as well as give patients a sense of control within the CT process.

In the CT decision-making process, trust was found to be an important component of the patient-oncologist relationship and influenced the decisions of both reflective and snap decision-makers. Patients who trusted their oncologists were more likely to seek their opinions about CTs and follow their recommendations. This trust, however, may be

29 For those patients who are not prepared to cope with full information, CT personnel might make sure these patients receive resources to deal with their emotions or acknowledge that there may be another, more appropriate time, to offer a CT.

30 Oncologists should not outright conclude a patient is unsuitable for a trial without first talking with the patient and offering appropriate supports and resources to help them deal with his/her fear and uncertainty.
problematic from a relational autonomy perspective when patients assume a trial is being offered with their best interest in mind and takes into account their individual circumstance (i.e., therapeutic misconception). Further, an overreliance by patients on the advice of their oncologists about CT participation due to being overwhelmed by the cancer experience has also been criticized as subverting patients’ relational autonomy.

On the other hand, deferring decision-making authority to an expert based on well-placed trust has been argued to be a legitimate expression of autonomy because it allows patients to use the expertise and advice of their healthcare providers to help them make informed CT decisions (Kukla 2007; de Melo-Martin & Ho 2008). Indeed, given the inherent power and knowledge differential inherent to the typical patient-oncologist/researcher relationship, expecting patients to make decisions on their own when they lack the experience and expertise has been argued to undermine their autonomy and cause patients to feel abandoned (Tomlinson 1986). Given the strong cultural imperative in societies like Canada for persons to be independent and directive (Kukla 2007), when patients are provided information and then left to their own devices and resources to “figure it out”, the concern about abandonment is a real one.\(^{31}\) The implication, however, is not for healthcare providers to be paternalistic. Rather, healthcare providers and the public should advocate for more resources and encourage models such as shared decision-making (Charles, Gafni, & Whelan 1997) to support patients’ relational autonomy, where patients and oncologists work together to make decisions.

\(^{31}\) Perhaps patients’ worry about being abandoned is contributing to their feelings of being overwhelmed and increasing the likelihood of them making snap decisions. More empirical research in this area is required in order to understand the nuances of this decision-making style.
Conflict of interest within patient-oncologist/researcher relationship. The dual role of oncologist-researchers, already discussed above in relation to therapeutic misconception, also raises concerns about conflicts of interest.\textsuperscript{32} The interests of an oncologist-researcher qua oncologist may conflict with his/her interests qua researcher. This conflict may cause the researcher to emphasize some aspects of trial participation and de-emphasize others (consciously or unconsciously). For example, oncologist-researchers may emphasize the therapeutic benefits of trial participation and underemphasize the limitations to personal care imposed by the trial design (e.g., random assignment, placebo-controls, double-blinding and procedures to measure study outcomes that have no benefit to participants) (Joffe & Miller 2006). In this way, conflicts of interest may jeopardize the trust relationship between the oncologist-researcher and the patient-participant (de Melo-Martin & Ho 2008).

In addition to the potential conflicts of interest engendered by their dual commitment to cancer care and scientific advancement, oncologist-researchers may also face conflicts related to secondary interests bound up with CT conduct. These include financial interests, such as consultant agreements or payment by drug companies, and renewal of public funding for their research programs. As Sollito \textit{et al.} (2003) argued, interests inherent to the research endeavour are also concerning. These interests include incentives for researchers to obtain groundbreaking findings, to be the first to publish on a new technique, or to have an article accepted by a prestigious scientific journal. Organizational interests are also important as

\textsuperscript{32} Conflicts of interest may arise “when activities or situations place an individual or institution in a real, potential, or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests” (CIHR 2010, p. 89)
continued recruitment and the success of current and future trials may contribute to an organization’s prestige and its ability to attract funding and talent. Again, these secondary interests may unconsciously influence how oncologists present or frame trials to patients with regards to what information is emphasized, the tone used to present information, and the level of enthusiasm displayed towards the trial. Furthermore, healthcare providers themselves are embedded in complex and power-laden relational dynamics within healthcare systems that may influence how they approach CT offers. For example, healthcare providers provide care to patients while also being subject to intense social pressure from their peers and working within a corporate healthcare system that is under significant financial constraints (Rodney & Varcoe 2002).

Significantly, patients, families and CT personnel in this study appeared largely unaware of potential conflicts of interest embedded in the research enterprise. The majority of patients, especially snap decision-makers, believed that oncologists were looking out for their best interests. Most did not consider the extent to which secondary interests might be motivating their oncologist. In fact, one patient with prostate cancer explained how his trust in his oncologist helped override his concerns about conflicts of interest (see Chapter Five). This patient acknowledged the possibility of pressure from the pharmaceutical company funding the study but felt his oncologist would protect him and not let it interfere with his work.

In sum, this section highlights the potential influence of real, potential or perceived conflicts of interest on patients’ and families’ CT decision-making processes, which also occur within a complex relational system. Given the additional recognition of secondary interests, the “No Wo/Man is an Island” model explained in Chapter Five might also be
capable of describing the relational autonomy of oncologists-researchers, who are not operating as isolated individuals but who have relational interests informed by the socio-political environment.

**Power in the Patient-Oncologist Relationship.** An essential component of a supportive social context for relational autonomy is the creation of a safe space for patients to voice their opinions and ask questions, particularly when they disagree with their oncologist (Dodds 2000). The positioning of oncologists as experts with authority, however, can make it very difficult for patients to ask questions that could be perceived as challenging. This asymmetry of power and authority is exacerbated by patients’ illness and social status. With oncologists being the main point of care for cancer treatment, patients have good reason for not wanting to disrupt this relationship. Patients with lower socioeconomic status, or who live in rural settings, may be even more reluctant to question or challenge their oncologists because these patients already have difficulty accessing care (LaVallie, Wolf, Jacobsen, & Buchwald 2008). Patients who are non-English speaking, or who come from a culture where asking questions of authority figures is considered particularly taboo, face additional challenges (Kohara & Inoue 2010).

Some patients and families in this study described feeling indebted to their oncologist for the successful treatment of their cancer. They wanted to reward or “give back” to their oncologist by participating in a trial. These families made exclamations during the interviews that the oncologist saved the patient’s life and likened their oncologist to “God” (see Chapter Five). These perceptions underscore the power and status differences between many patients and their oncologists, and raise questions about their ability to ask challenging questions.
It is important to note, however, that power was also bi-directional. Some patients recognized their personal authority to accept or refuse the offer to participate in a CT. Most patients were aware of the fact that their oncologists needed to recruit participants in order to fulfill their roles as researchers. Furthermore, most patients valued their relationship with their oncologists. A decision to enrol in a study in order to “give back” could be consistent with relational autonomy insofar as the decision was motivated by a genuine desire to support an important and longstanding relationship. Also, these patients were able to exercise their capacities for relational autonomy in other ways. For example, patients weighed the potential for adverse physical effects and reflected on negotiating logistical challenges in order to make a considered decision. Notwithstanding their genuine desire to honour their relationship with their oncologist, their decision to participate was contingent upon the safety of the trial and their ability to fit trial participation into their lives.

Therefore, influencing factors such as power in the patient-oncologist relationship are not necessarily undermining of patients’ relational autonomy in CT decisions when patients are still able to exercise their skills and capacities for autonomy (e.g., self-reflection, analytical skills, self-worth) to a significant degree and in response to these influences. However, this requires that patients have already been provided the opportunity and resources to develop these skills, and have been able to maintain these skills over time with the help of a supportive sociopolitical environment.

**Family influence.** Families may support and undermine patients’ relational autonomy in several ways. Foremost, familial relationships can support relational autonomy when family members help patients to make decisions that are in line with their own (the patient’s) values and preferences by facilitating their capacities for autonomy (e.g., assisting patients in
identifying and analyzing CT information). In addition, patients’ relational autonomy is supported when family members are able to persuade patients to revise their preferences related to CT participation in response to important information.33

In contrast, familial relationships can undermine a patient’s relational autonomy when family members pressure or bully patients into making decisions against their wishes, or when family members are abusive or neglectful, thus not allowing patients to develop or exercise their capacities for autonomy (Ho 2006). In some cases, pressure or bullying may be obvious. In others, however, pressure may be implicit and more difficult to detect. This is especially the case when patients are not fully aware that they are being subtly influenced or when they have been acculturated to believe they lack moral worth and/or the ability to make their own choices (Hyun 2002). For example, in some families, males may be given the authority to make medical decisions on behalf of female patients. If a family is historically neglectful in promoting its female members’ abilities to understand themselves as worthy or capable of determining for themselves which values, beliefs, and preferences they want to guide their CT decision-making process, then female family members’ relational autonomy may be undermined.

It is important to recognize, however, some female patients may prefer to delegate their decision-making authority to their husbands or other male family members. This preference may be a result of a value system in which family members care for one another

33 Here, persuasion involves the provision of reasons or opinions that promote understanding. Persuasion promotes relational autonomy since the patient exercises her capacities to determine for him/herself whether the reasons or opinions of others are worth accepting or discarding as motives for action (Sherwin 1998).
and make decisions with respect to communal values. If a female patient shares the same values as her husband, and she does not necessarily feel unable to make her own choices or restricted in her autonomous capacities, then delegation could be a legitimate expression of her relational autonomy. However, in accordance with Sherwin’s theory of relational autonomy, if the shared values implicitly undermine the female patient’s sense of self-worth, then this is problematic because self-worth is a necessary condition of autonomy (Sherwin 1998).

The difficulty for healthcare providers and CT personnel, however, is how to respond to a family situation that undermines autonomy without causing more harm to the female patient. If a patient is being pressured by family members to delegate her decision, and she does not want to upset the family, then healthcare providers may need to acknowledge the family’s reasoning process and explore possible options that may respect everyone’s wishes (see, for e.g., Ho 2008). This approach would respect the family relationship and encourage the reasoning to take into account a female patient’s perspective, thus respecting her self-worth.

The majority of patients in our study wanted to know their family’s opinions about CTs in order to assess whether they would be imposing a burden on family members if they were to participate. From a relational autonomy perspective, this apprehension demonstrated patients’ sense of interconnectedness between themselves and family members and the fact that their interrelated interests create a sense of mutual obligation. However, the concern is whether this sense of obligation towards family overrides a patient’s capacities for autonomy.

The extent to which family members support or undermine patients’ autonomy depends upon the extent to which family members’ opinions detract from or support patients’
abilities to consider CTs from their own perspective. If a patient reflects upon the reasons and opinions offered by family members (thereby exercising autonomous capacities such as self-reflection), and takes them up as his/her own, family have supported this patient’s relational autonomy. In contrast, if the opinions of family members are not reflectively endorsed by the patient, and are simply imposed from without (demonstrating a lack of respect for the moral worth of the patient), then familial relationships may work to undermine the patient’s relational autonomy to a certain degree (Sherwin 1989; Hyun 2002).

In this study, CT personnel identified situations where patients’ families, usually spouses, made decisions for them. In some cases, this decision appeared to be a reflective decision on the part of a patient, and an enactment of his/her self-worth. As mentioned previously, deferral of decision-making authority may be a legitimate expression of autonomy; different patients can value different decision-making approaches (Degner & Sloan 1992). In other cases, however, CT personnel expressed concern that some wives of prostate cancer patients were making decisions out of their own interests rather than considering the best interest of the patient (see Chapter Four). Again, insofar as family members fail to consider and respect the patient’s own moral worth and capacities for autonomy, their behaviour may undermine the patient’s relational autonomy.

In another interesting case, a patient reflectively revised her preferences concerning CT participation in light of her daughter’s beliefs and values. In this case, a breast cancer patient’s daughter was upset upon learning that her mother was considering a trial (see Chapter Five). The daughter did not want her mother to participate because she was scared the experimental intervention would cause her harm. The patient discussed the trial with her family, and after hearing her daughter’s concern, promised that she would only participate in
the trial if she was randomized to receive standard care. This case is interesting because it clearly illustrates how a family member can influence a patient’s decision in a manner that is supportive, rather than undermining, of relational autonomy. Having listened to her daughter’s concerns, the patient reflectively revised her position vis-à-vis CT participation, setting limits on the conditions under which she would participate. This example demonstrates the fundamentally relational character of the self since the patient shared her daughter’s interests in the wellbeing of her family and revised her preferences accordingly.

**Theme D: Gender and Decision Making**

Gender had a subtle influence on the CT decision-making process and was seen to both support and restrict patients’ relational autonomy. However, it is important to acknowledge that gender and type of cancer was conflated in this study. Therefore, gender differences may be reflective of differences related to disease and treatment. Future research will need to further explore the influence of gender on CT decision making.

In general, gender norms (e.g., women are more willing to seek help and are more emotionally expressive than men) may support patients’ relational autonomy when they encourage patients’ autonomous capacities. For example, a gender norm is supportive of a patient’s relational autonomy when it encourages a patient to consult with others who hold expertise and information about CTs. In contrast, gender norms may negatively influence patients’ relational autonomy when they do not allow patients to make reflect on their values and interests or when patients are made to question themselves as capable of defining their own interests. Patients’ relational autonomy may be further restricted when gender roles limit the opportunities available for patients to develop their capacities for autonomy. This study revealed multiple ways in which gender influenced patients’ CT decision-making process.
**Gendered responses to the research endeavour.** The current study findings demonstrated patients’ internalization of their personal responsibility to contribute to the research endeavour. This was explained throughout both men and women’s interviews, where reference was made to research participation as an obligation or moral duty, to participate as others have done so before (see Chapter Five). The responsibility for advancing the research agenda, however, appeared to be received differently by women than for men. This was starkly demonstrated when some women in this study voiced concerns about not living up to the image of motherly caregivers if they did not participate in a CT. Social and cultural practices that readily cast women as caregivers, even when they are in need of care (e.g., Hooymen 1990), may be influencing this gender norm and restricting female patients’ relational autonomy. Several women felt it difficult to focus on their clinical situation and expressed distress and guilt when they chose not to participate in a CT because it meant they were not helping others. Gender norms may, therefore, have undermined women’s ability to self-reflect and made them question the value of their own interests. However, these women were ultimately able to consider their own preferences, but it took significant support from their family or oncologist to help them overcome gender socialization. For example, in one case, a woman’s husband gave her permission to accept that the whole family was burned out from attending her treatments. This woman’s “own interests” overlapped with her family’s interest and together they were able to decline a CT because it was what was best for everyone’s mental and physical health.

The majority of male patients with prostate cancer did not report similar feelings of anguish and guilt. It is not clear from the data why this was the case. Perhaps it is more socially or culturally acceptable for men to consider their personal or familial situation and
reject a CT offer because ‘doing right for me’ is more aligned with masculine norms (Schofield, Connell, Walker, Wood & Butland 2000; Courtenay 2000).

**Gender and the CT decision-making process.** Gender norms also influenced various phases and processes of patients’ CT decision making. In discussing their predisposing attitudes towards CTs, men more often mentioned being open to participating because they wanted to be on the “leading edge” of cancer treatment (see Chapter Five). Also, in the later sub-process of grappling with uncertainty, men were more likely to want to take risks given fewer treatment options. As one man explained, “no venture, no gain” (see Chapter Five). He later also explained that it requires courage to leap into the unknown. Such perspectives were more likely to reflect a sense of competition and risk-taking consistent with masculine traits in order to advance cancer therapy and receive potential benefit (see, for e.g., Oliffe 2005; Oliffe 2006).

Men were also more likely to position themselves as the “patriarch of the system” (see Chapter Five) but were open to receiving help from their wives in their decision-making process. Spouses coordinated and accompanied men to appointments, took detailed notes, and asked questions of the oncologist or CT personnel (thus, perhaps demonstrating feminine norms of ‘caring for’ their partners). This may reflect a larger gender issue where men typically do not engage in health care and rely upon others for their decision making (Galdas, Cheater & Marshall 2004).

When weighing pros and cons, women in this study reported taking stock of their relational environment and more often considered which option (CT or standard care) would allow them the best chance for being around for their family or children. This reflects their dominant social role and responsibility as caregivers for their families (Schofield *et al.* 2000).
Women were more often the primary caretakers and so they needed to balance childcare responsibilities with their own healthcare. Similarly, several men that took part in the study made reference to making a CT decision that would prolong their life in order to support the preservation of important relationships (e.g., be around for their grandchildren). Many men also focused on practical aspects of their family relationship, such as maintaining their financial responsibility to their family.

In sum, social roles had an impact on both men and women’s CT decision-making processes. Women were more likely to be responsible for childcare and this posed constraint for some women in considering CTs who were single parents and had limited social resources. Other women, however, agreed to take part in CTs so they could live and be around to take care of their children. Men’s relational autonomy may have been undermined to the extent they felt pressure to identify with being a ‘risk-taker.’ This may have been influenced by gender socialization that rewards men for demonstrating this masculine trait and restricted their opportunity to consider other (i.e., non-masculine) reasons for participating or not in CTs.

**Clinical Implications**

Several avenues for enhancing patients’ relational autonomy within CT recruitment procedures follow from the “No Wo/Man is an Island” theoretical model and analysis. The first clinical implication involves the development of targeted CT personnel education around CTs to address potential biases regarding how information about CTs is communicated and how patients are recruited. This relates to the integral role of CT personnel in supporting patients’ relational autonomy and that positive or negative framing,
as well as therapeutic misconception, may place undue influence on some patients’ autonomy within the CT decision-making process.

In addition to education for CT personnel and oncologists regarding communication and recruitment, training and interdisciplinary collaboration is needed to improve cancer patients’ access to supportive care, especially for more marginalized patients. This will help to address some of the structural inequities in cancer care access as well as support the social conditions for patients’ autonomy by helping them cope with their emotions related to their cancer experience.

The third clinical implication is related to patient education around CTs. Specifically, educational resources, such as information booklets written in lay language, are needed to promote patients’ (and families’) understanding about the potential for therapeutic misconception and also to explain the differences between types of trials so that patients have the opportunity to be more informed prior to the CT offer. The “No Wo/Man is an Island” theoretical model identified several social and structural influences on patients’ misunderstandings about research. Therefore, even though this clinical implication is targeted at patients and families, it is important to recognize the larger context in which this problem is situated, and that similar education materials could also be developed for healthcare providers and policy-makers.

Lastly, macro-level strategies to address structural barriers that are potentially undermining of cancer patients’ autonomy are suggested, such as improving access to quality healthcare, cancer therapies and CTs. Patients’ CT decision-making processes are not independent from the healthcare and CTs systems; instead, the larger socio-political environment influences patients’ autonomy and CT decision-making processes.
Since personal, social and structural issues overlap to influence patients’ relational autonomy, a multi-pronged strategy in these areas is required.

**Education for CT Personnel**

Providing education to CT personnel recognizes the integral role of these providers in supporting patients’ relational autonomy within their CT decision-making process. Specifically, further education regarding how CT personnel should frame trials in a non-judgmental manner is required. This may include training that helps them identify and address their assumptions and biases about the competence of marginalized populations, and how non-verbal behaviour may influence patients’ decisions about CTs.

Thorne, Hislop, Armstrong and Oglov (2008) recognize the tone and setting for communication is central to managing cancer patients’ fear and has the power to harm or heal. Patients with cancer typically experience strong emotional responses to their illness experience compared to other diseases. While patients’ experience of fear is very real, the information that gives rise to that fear could be based on inflated perceptions of risk stemming from social norms or beliefs about cancer. This could be because cancer is often equated with death, causing patients to experience a heightened sense of fear and looming mortality (Sontag 1977). Therefore, healthcare provider training could be specifically tailored to address not only overt communication but also underlying beliefs stemming from potentially inaccurate information that influences patients’ perceptions of CTs and how they experience their illness.

Healthcare providers could also empower patients with decision tools and resources that support patients’ engagement in CT decisions and discussions about their beliefs and values. For example, question prompt lists could be provided to patients prior to consulting
with CT personnel to help guide the CT conversation and ensure patients’ concerns are addressed (see, for example, Brown et al. 2012). These inexpensive decision interventions support patients in identifying any questions or concerns they have about CTs and allow CT personnel to provide accurate information to address patients’ needs.

How to communicate to patients and families about potential secondary interests (i.e., desire to publish, achieve groundbreaking findings) could also be a part of healthcare provider training initiatives, as well as how to discuss or tailor potentially distressing information without causing them further harm. Further, since not all patients will be able to understand risk information in terms of probabilities and statistics, education regarding other means of expressing risk is imperative (e.g., Fischhoff 1999). For example, professional training developed by Brown et al. (2007) and Bernhard et al. (2012) regarding how to frame conversations about informed consent in the context of cancer CTs addressed both risk perception and disclosure of interests. This training could enhance communications skills in both physicians and CT personnel.

Education for CT personnel could be incorporated into existing training programs as a distinct module or within pre-existing program sessions and workshops. For example, the NCIC Clinical Trials Group offers a three-day face-to-face course for new clinical investigators using lectures and interactive training methods. The fundamentals of recruitment offered in this course could be enhanced by role-playing, where CT personnel introduce trials and identify their non-verbal cues, biases and assumptions, followed by group discussion of the social and structural barriers to cancer patient autonomy within the context of CTs. Another option could be the incorporation of these strategies into online training opportunities. The National Cancer Institute (NCI) provides education and training for health
professionals and researchers in the areas of clinical trial accrual and ethical research involving human participants.\textsuperscript{34} Course material could be expanded to cover secondary interests, and include case scenarios to demonstrate different risk communication strategies, and their potential impact on patient accrual and relational autonomy.

Finally, education about ways to enhance interdisciplinary collaboration to support patients’ relational autonomy may also be important. First, opportunities to involve other healthcare providers in supporting patients’ understanding or addressing psychosocial distress during or prior to the CT offer may be necessary. For example, incorporating cancer distress screening into discussions about CTs and coordinating services for patients to address their unique psychosocial needs may offer valuable support to anxious patients (see Canadian Partnership Against Cancer\textsuperscript{2009}). Some authors have suggested that professional navigators could play a pivotal role in providing follow-up care with more anxious patients to help coordinate available psychosocial care and supportive services to address their unique needs (see, for example, Fillion, Cook, Blais \textit{et al.}\textsuperscript{2011}). Second, additional trial personnel could be assigned to assist specifically disadvantaged groups. This is especially important given the lack of time individual oncologists have to spend with patients in discussing trials while recognizing that some cancer populations may need more support to actualize full autonomy.

\textbf{Patient education around CTs.} Patient education about trials is also important. A national database that allows patients to search trials currently open in their province would be a useful source of information. Furthermore, patients could access this resource on their own time and from anywhere in the province or country. Recently, Health Canada (2013)\textsuperscript{34} See NCI website, accessed September 30, 2013 at http://www.cancer.gov/clinicaltrials/conducting.
established a clinical trials database where the public can access basic information about Phases I to III cancer trials. This is a useful first step, but patients are still forced to contact the trial sponsor to obtain comprehensive information about patient enrolment criteria and CT sites. A database with more detailed information about trials (such as eligibility criteria) would be valuable. The utility of this database is also limited by low visibility. Further marketing of this database as a resource for patients is necessary, so that more patients are aware of this information and know how to access it.

Therapeutic misconception was a major theme in this study. Since therapeutic misconception is a serious threat to relational autonomy, targeted education about the therapeutic misconception is required. A national pamphlet—“Cancer Clinical Trials and You”—could be developed in lay language that discusses eligibility criteria, the difference between trials and standard care, and the different trial phases available. It could also define key words such as placebo and randomization. In addition, it could explain up front that the trial decision will have no bearing on the care that patients will receive from their oncologist. A representative from the National Cancer Institute of Canada’s (NCIC) Clinical Trial Group, who is not directly associated with a cancer clinic or agency, could be listed as an information resource for patients with remaining questions. This could equalize power relations during CT recruitment by empowering patients with extra resources and accessible information.

Finally, there could be larger discussion or an education campaign around how research is structured and carried out. Podcasts about cancer trials could be created that invites discussion from national and international investigators as well as the public to explore perceptions of trials in an open and accessible manner. These could be especially
useful for rural populations because they could be accessed online at their convenience. 
However, campaigns will need to be cautious about marketing only the potential benefits of 
drug trials per se, thereby encouraging public understanding that may not reflect the actual 
nature of the particular trial intervention and associated risks/benefits. The National Cancer 
Research Institute in the United Kingdom has some effective education and outreach 
programs that Canadian CT personnel and policy-makers could draw upon in order to shift 
CT practices and raise awareness in the community around CTs.\textsuperscript{35} Also, the American 
Cancer Society has a webpage identifying new discoveries in breast cancer research where 
they explain the different types of research available (e.g., radiation, chemotherapy and 
targeted drugs).\textsuperscript{36}

\textbf{Strategies to address access issues and structural barriers.} A main structural 
influence on the relational model of patients’ CT decision making was oncologists’ lack of 
time to discuss trials with patients and families. Decision aids around CT enrolment (see 
O’Connor \textit{et al.} 1999; O’Connor \textit{et al.} 2007) or a national website with frequently asked 
questions about CT participation, could facilitate information sharing outside of the patient-
oncologist discussion. Patient navigator roles for CTs may be another useful strategy by 
having a dedicated healthcare professional provide patients with consistent and 
individualized support. The development of other support services, such as psychosocial care 
to help patients and families manage their fear and distress, may better equip cancer patients 
to receive information about CTs (Cancer Journey Action Group 2009).

\textsuperscript{35} See the National Cancer Research Institute website, accessed September 20, 2013 at: \url{http://www.ncri.org.uk}.

\textsuperscript{36} See the American Cancer Society webpage, accessed March 8, 2014 at: \url{http://www.cancer.org/cancer/breastcancer/overviewguide/breast-cancer-overview-new-research}. 
Pan-Canadian adoption of distress screening and management practice guidelines are important to detect distress and determine whether a patient needs further assessment or referral for supportive care (Canadian Partnership Against Cancer 2012). This is particularly important to also address CT personnel’s potential biases, given research that has demonstrated that oncologists currently may not be the best identifiers of distress and may actually over-estimate distress in lower income populations (Sollner et al. 2001).

To enhance rural cancer patients’ access to CTs, additional resources for patient accrual are necessary. For example, stipends for travel would make CTs more accessible for rural cancer patients or those from lower socioeconomic backgrounds. At the macro-level, patients who are perceived by recruiting oncologists to lack decisional capacity, such as those with mental health and addictions or who “live alone” without spousal support, might have had a better chance for a trial if there were a stronger welfare system in place as well as a national strategy to better the quality of life for persons living in poverty and with mental illness and addictions (see, for example, the recommendations from the Mental Health Commission of Canada 2012).

Finally, ensuring a more accessible and higher quality health care and social services overall is extremely important since this research identified larger issues related to drug policy, healthcare access, child care policy, social housing, transportation and workplace policy as influences on patients’ CT decision-making process. With regards to health care, cancer patients’ relational autonomy is potentially undermined due to the fact that they are making decisions within a public healthcare system in which treatment options and services are limited. These constraints may cause patients to feel they have little choice but to agree to CTs that offer access to therapies and follow-up care that would not be available otherwise.
Addressing these challenges could include improving access to cancer survivorship programs and the development of patient care plans following treatment completion to minimize cancer patients’ distress and help them connect to community resources for coping with their disease. Standardization in cancer drug approval and access to proven therapies across Canada is also required, as well as better monitoring and follow-up cancer care so that patients do not feel they need to enrol in CTs in order to access services.

Inequities in social services also have a profound impact on Canadian cancer patients’ relational autonomy in the context of CT decisions. For some patients, particularly women with children, a lack of childcare can make attending additional clinical appointments to participate in CTs difficult if not impossible. Other patients may not be able to participate in trials if their work places do not provide disability insurance so that they can take time off to seek treatment and participate in trials. Those individuals who are unemployed and/or underemployed or retired with limited cash flow would also have difficulty since there would be additional costs of transportation to and from the study site, especially if it involved a long commute from a rural setting.

Addressing such inequities through the development of fair and equitable social policy will support patients’ relational autonomy related to health care decisions, including CT decisions. Practically speaking, the provision of basic services such as health care, education and a decent standard of living can go a long way in reducing health and social disparities when it is also paired with a focus on poverty reduction and targeted interventions for various life-stages, such as early-childhood development (Blas et al. 2008; Johnson et al. 2008). A specific example to ensure a decent standard of living and health care access includes addressing the unemployment or underemployment in various groups to allow them
access to fair wages and disability insurance if they were to get sick with cancer, would impact their relational autonomy and provide them with overall more meaningful health options.

**Limitations**

This research has a number of limitations. First, it employed qualitative research methods and purposive sampling. As such, the findings must be viewed as providing a beginning foundation to launch additional decision-making studies with more diverse cancer populations. Second, sampling was restricted to one urban clinical facility, which limits the generalizability of the results to other geographical regions. This decision was made to ensure the feasibility of the study and limit the heterogeneity of the data with regards to unique socio-political contexts that may exist across cancer care centres and provincial healthcare systems. Third, this study exemplifies the difficulties in recruiting, since I was only able to recruit patient and support person participants that were mostly white, upper middle class, patients with post-secondary education (i.e., university, graduate, or professional degree (n=27). Also, recruitment was restricted to English speakers. However, this research did benefit from CT personnel’s historical perspectives of trial decision making involving marginalized patient groups not included in this study. Additional research is required, however, to determine the extent to which the study findings are generalizable to a broader sample. Fourth, for the study investigating CT personnel’s perspectives (Chapter 4), no demographic information was collected beyond role and gender. This is a possible limitation where experience and education may have influenced CT personnel’s perceptions. Within the grounded theory study (Chapter 5), participants’ time from diagnosis and the treatments they received were not systematically collected. There may also be a recall bias
insofar as several participants were several years away from their initial cancer diagnosis. Additionally, the type of trial that participants were making decisions about was not formally assessed. Type of trial may have greatly influenced the CT decision-making process because of the different risks associated with exercise versus drug trials. Finally, data saturation was not reached with those individuals who declined and withdraw from CTs in this study due to the difficulties in recruiting these populations within the context of a PhD dissertation.

Finally, this research makes practical suggestions to support patients’ relational autonomy that require financial resources that the current Canadian healthcare system can ill afford. Therefore, operationalizing solutions may require some creativity. More research needs to be conducted on developing innovative strategies that would engage, for example, oncology residency programs so CT personnel training can be imbedded in already existing programs. In order to support rural patients’ access to CTs, it might be fruitful to take advantage of already existing communities of practice. Oncology family practice networks, for example, could take responsibility for data collection so rural and remote patients would not need to travel to an urban centre for the study. Also, better coordination of CTs across rural settings could occur so that if a CT nurse does travel, he or she could combine data collection across multiple communities. If CT personnel cannot travel to where patients are, then perhaps CT personnel could engage members of the interdisciplinary care team (i.e., social workers) to identify temporary, low-cost housing in urban settings for patients with cancer to stay while participating in CTs. Finally, patient navigators are healthcare providers that are already being implemented to enhance cancer patients’ experience of their treatment trajectory. Perhaps this service could be expanded to include support for patients who are making decisions about CTs.
Conclusion

Cancer CTs play an essential role in advancing knowledge and improving patient care and outcomes. While much attention has been given to the reasons why patients participate or not in CTs, this dissertation research has explored the socio-political influences on cancer patients’ CT decision-making process through the lens of relational autonomy. Study findings illustrate how individuals’ CT decisions are situated within a larger relational and socio-political context that is characterized by inherent power differentials, social injustice and systemic inequalities. Strategies to address barriers to patients’ relational autonomy in the context of CTs must, therefore, attend to not only the personal, but also the social and structural environment. For example, findings from this research can inform the development of more sensitive recruitment procedures that acknowledge the relational and socio-political nature of CT decisions. Other strategies can include education for CT personnel and patients, and structural supports (e.g., patient navigators for CTs, distress screening, and better quality healthcare and access to CTs). These strategies can address the power relationships, social injustice and systemic inequities identified in order to support patients’ relational autonomy in the context of CT decision making.

Future Research

Ultimately, it is difficult to say with certainty whether some factors and contexts within cancer patients’ CT decision-making processes undermined or facilitated their relational autonomy. For example, in this study, whether some patients experienced optimistic bias (potentially undermining of autonomy) or demonstrated a “glass is half full” dispositional trait (potentially facilitating autonomy) is difficult to determine without more nuanced examination. More targeted research that investigates patients’ beliefs and attitudes,
and the specific social and structural contexts influencing therapeutic optimism, is required in order to make definite assessments about the impact on patients’ relational autonomy.

Similarly, in the context of spouses’ involvement in making CT decisions for their partners, future research could investigate which values were shared, and the extent to which spouses consult with patients. Where social norms (e.g., gender, culture, religion) are involved, it will be necessary to examine the historical formation of patients’ values and preferences in order to make determinations about whether “traditional beliefs” (e.g., men making decisions on behalf of women) are undermining or supportive of patients’ intrinsic self-worth. This research requires detailed attention to the influence of social complexity (family/cultural dynamics) and structural influences on individual patients’ self-determination that was not feasible in this study.

Future research could also look more closely at relational autonomy within specific marginalized populations (e.g., persons with mental illness, persons from rural areas). Results from the current study indicate that some groups were excluded from trial participation for social and structural reasons built into pre-screening practices. These practices would benefit from further analysis, including an analysis of CT personnel’s biases and assumptions that led to pre-screening. Research could also explore the various nuances of CT decision-making for Phase I trials, which are known to be more ethically problematic because patients are more vulnerable and there is a greater concern about therapeutic misconceptions. Finally, future research related to cancer patients’ CT decision-making process in additional study sites across Canada would allow the “No Wo/Man is an Island” theoretical model to be further elucidated and tested in different cancer populations.
This research has been the first known study to examine cancer patients’ CT decision-making process from a relational autonomy perspective. Study findings revealed the complex nature of CT decision making, and how cancer patients’ CT decisions are situated within a larger relational and socio-political context that is characterized by inherent power differentials, and social and structural inequities. In particular, apparent power differentials between patients and physicians, therapeutic misconception, and inequities in access to CTs challenge cancer patients’ abilities to exercise their relational autonomy within their CT decision-making process. Practice implications of this research include targeted education for CT personnel and patients to equalize power relationships within CT recruitment. In addition, standardization of cancer drug approval, better monitoring and follow-up cancer care, and ensuring a more accessible and quality healthcare system can address structural barriers and support patients’ relational autonomy within the context of CTs. Empowering cancer patients’ relational autonomy in these ways will allow patients to feel more supported in their overall health care experience, and has the potential to allow patients who are interested to take part in well-designed CTs. Furthermore, addressing social inequities as part of supporting cancer patients’ relational autonomy has the potential to improve representation of all cancer patients in CTs – thus enhancing the state of cancer science and improving evidence-based cancer care.
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Appendix I: Recruitment Poster

WHO: Breast or prostate cancer patients with early or locally advanced disease who have accepted, declined, or withdrawn from a clinical trial.

WHAT: We are interested in understanding what influenced your decision and how to best support you in your decision-making process.

HOW: You are invited to participate in a 1 hour interview where you will be asked questions on this topic. A $25 honorarium will be provided.

For more information about this study, please contact Ms. Jennifer Bell at [phone] or email her at [email].
Appendix II: Permission to Contact Patients

Permission to Contact (Patients)

Title of Study: Relational autonomy and decision making: Improving clinical trial enrolment in cancer care

Principal Investigator:
Lynda Balneaves, PhD, RN, Associate Professor, School of Nursing, UBC  604-822-7679

Co-Investigators:
Jennifer Bell, MA, PhD Student, Centre for Applied Ethics, UBC  604-707-5960
Anita Ho, PhD, Assistant Professor, Centre for Applied Ethics, UBC  604-822-4049
Harriet Richardson, PhD, National Cancer Institute of Canada – Clinical Trials Group and Assistant Professor, Queens University  613-533-6430
Kim Chi, MD, Clinician Scientist, BC Cancer Agency  604-877-6000 (672746)

We are interested in exploring what it was like for you to make a decision about whether or not to participate in a clinical trial. The primary purpose of this study is to develop decisional support strategies for patients having to make difficult decisions about trial participation.

We will be conducting individual interviews with patients that will last 60-90 minutes to hear about your decision-making experience. You will be paid a $25 honorarium for your time.

Do you give permission for one of the study investigators to contact you?
(Check mark one)

___ Yes, I am interested in the study and give permission for you to contact me.

___ No, I am not interested.

Please Print Name

Address

Date

Phone Number (Primary)

Phone Number (Cell)

Kindly return form to the clinical trial personnel at the VC-BCCA. If you have any questions about the study, please feel free to contact the Principal Investigator at 604-822-7679
Appendix III: Patient Information Package

What do I do if I want to take part in the IMPACCT study?

Review the letter of invitation and consent form

Contact the Project Director, Jennifer Bell, at [phone] or [email]. She will arrange an interview time that is convenient for you.

Arrive at your scheduled interview, at the CAMEO office (9th floor, Fairmont Medical Building, 912-750 West Broadway Ave., Vancouver, see attached map)

Meet with your interviewer and sign the consent form.

Take part in the interview.

Thank you very much for your time!
Appendix IV: Letters of Explanation

Letter of Explanation (Patients)

Title of Study: Improving patient autonomy in cancer clinical trials (IMPACCT)

Principal Investigator:
Lynda Balneaves, PhD, RN, Associate Professor, School of Nursing, UBC 604-822-7679

Co-Investigators:
Jennifer Bell, MA, PhD Candidate, Centre for Applied Ethics, UBC 647-462-2797
Anita Ho, PhD, Assistant Professor, Centre for Applied Ethics, UBC 604-822-4049
Harriet Richardson, PhD, National Cancer Institute of Canada – Clinical Trials Group and Assistant Professor, Queens University 613-533-6430
Kim Chi, MD, Clinician Scientist, BC Cancer Agency 604-877-6000 (672746)
Karen Gelmon, MD, Senior Scientist, BC Cancer Agency 604-877-6098 (2045)

We are interested in exploring what it was like for you to make a decision about whether or not to participate in a cancer clinical trial. The primary purpose of this study is to develop decisional support strategies for cancer patients having to make difficult decisions about trial participation.

We will be conducting individual interviews with patients that will last 60 minutes to hear about your decision-making experience. You will be paid a $25 honorarium for your time.

If you are interested in hearing more about the study and what your participation would involve, please call the Graduate Research Assistant, Ms. Genevieve Breau, at [phone] or email her at [email].

Sincerely,

Lynda G. Balneaves, RN, PhD
Associate Professor, UBC School of Nursing
Letter of Explanation (Support Persons)

Title of Study: Improving patient autonomy in cancer clinical trials (IMPACCT)

Principal Investigator:
Lynda Balneaves, PhD, RN, Associate Professor, School of Nursing, UBC 604-822-7679

Co-Investigators:
Jennifer Bell, MA, PhD Candidate, Centre for Applied Ethics, UBC 647-462-2797
Anita Ho, PhD, Assistant Professor, Centre for Applied Ethics, UBC 604-822-4049
Harriet Richardson, PhD, National Cancer Institute of Canada – Clinical Trials Group and Assistant Professor, Queens University 613-533-6430
Kim Chi, MD, Clinician Scientist, BC Cancer Agency 604-877-6000 (672746)
Karen Gelmon, MD, Senior Scientist, BC Cancer Agency 604-877-6098 (2045)

We are interested in exploring what it was like for you to support a family member or friend in making a decision about whether or not to participate in a cancer clinical trial. The primary purpose of this study is to develop decisional support strategies for cancer patients having to make difficult decisions about trial participation.

We will be conducting individual interviews with support persons that will last 60 minutes to hear about your decision-making experience. You will be paid a $25 honorarium for your time.

If you are interested in hearing more about the study and what your participation would involve, please call the Graduate Research Assistant, Ms. Genevieve Breaux, at [phone] or email her at [email].

Sincerely,

Lynda G. Balneaves, RN, PhD
Associate Professor, UBC School of Nursing
Letter of Explanation (Clinical Trial Personnel)

Title of Study: Improving patient autonomy in cancer clinical trials (IMPACCT)

Principal Investigator:
Lynda Balneaves, PhD, RN, Associate Professor, School of Nursing, UBC 604-822-7679

Co-Investigators/Collaborators:
Jennifer Bell, MA, PhD Candidate, Centre for Applied Ethics, UBC 604-221-6551
Anita Ho, PhD, Assistant Professor, Centre for Applied Ethics, UBC 604-822-4049
Harriet Richardson, PhD, National Cancer Institute of Canada – Clinical Trials Group and Assistant Professor, Queens University 613-533-6430
Kim Chi, MD, Clinician Scientist, BC Cancer Agency 604-877-6000 (672746)
Karen Gelmon, MD, Senior Scientist, BC Cancer Agency 604-877-6098 (2045)

We are interested in exploring what it was like for cancer patients to make a decision about whether or not to participate in a cancer clinical trial. The primary purpose of this study is to develop decisional support strategies for cancer patients having to make difficult decisions about trial participation. We would appreciate hearing from you as a clinical trial personnel about your insights into patients’ decision making about clinical trial participation and what may be best practices in terms of supporting patients in making these decisions.

We will be conducting individual interviews with clinical trial personnel that will last 30 minutes.

If you are interested in hearing more about the study and what your participation would involve, please call the Project Director, Ms. Jennifer Bell, at [phone] or email her at [email].

Sincerely,

Lynda G. Balneaves, RN, PhD
Associate Professor, UBC School of Nursing
Appendix V: Consent Forms

Consent Form (Patients)

Title of Study: Improving patient autonomy in cancer clinical trials (IMPACCT)

Principal Investigator:
Lynda Balneaves, PhD, RN, Associate Professor, School of Nursing, UBC 604-822-7679

Co-Investigators:
Jennifer Bell, MA, PhD Candidate, Centre for Applied Ethics, UBC 647-462-2797
Anita Ho, PhD, Assistant Professor, Centre for Applied Ethics, UBC 604-822-4049
Harriet Richardson, PhD, Assistant Professor, NCIC Clinical Trials Group 613-533-6430
Kim Chi, MD, Clinician Scientist, BC Cancer Agency 604-877-6000 (672746)
Karen Gelmon, MD, Senior Scientist, BC Cancer Agency 604-877-6098 (2045)

Purpose:
The primary purpose of this study is to develop decisional support strategies for patients having to make difficult decisions about taking part in clinical trials. The overall aims include: 1) understand how cancer patients’ make decisions about clinical trial participation; 2) explore the personal, social, and health care factors that influence what is important to cancer patients in making decisions about clinical trial participation; and 3) identify how health care professionals can best support cancer patients’ decision making about clinical trials. In this study, we will be talking to patients and support persons (i.e., family members) as well as health care professionals.

Study Procedures:
In this study, you will be asked to participate in a 60 minute interview that will explore your decisions about taking part in a clinical trial (i.e., a study examining the effects of a treatment). You will be asked about your experience in making this decision, what factors were important to you in this decision, and who was involved in your decision. You will also be asked to talk about what was challenging about this decision and any recommendations you may have about how this decision could have been better supported by health professionals. The interview will be digitally recorded and then transcribed. You will be paid a $25 honorarium for your time. You may be contacted after the interview and invited to take part in a 60 minute focus group with other patients to discuss the draft study findings and to provide input. You are not required to take part in the focus group if you so choose.

Project Outcomes:
Although the project outcomes will be determined by the research findings, possible research products will include: journal articles and reports for health research and clinical trial staff members, as well as for the general public. The information we get from this study might be used again for more research on clinical trial participation, but only if approved by the appropriate university committees.
Risks and Potential Benefits:
There are no explicit benefits or direct risks to you by taking part in this study. However, the interview or focus group will provide you with the opportunity to voice your opinion on your experiences. If the interview or focus group raises issues or feelings that you would like support in dealing with, the researcher can refer you to a counselor, or to other resources in the community. You can terminate your participation at any time, and you do not have to answer any questions that make you feel uncomfortable.

Confidentiality:
We will keep your name and information you provide strictly confidential. We will not use your name in the research reports and we use pseudonyms and codes instead of your name or other personal information in our notes and typed copies of the interview transcripts. Any documents and/or computer files linking your name to the pseudonym or codes will be kept separate from the data. All hard copies of documents will be identified only by code number and kept in a locked filing cabinet at the University of British Columbia. Electronic records will be kept on the local hard drives of team members’ office computers – all of which are password protected. The information collected in this study may be used for teaching purposes without revealing any information that would identify you.

Contact for information about the study:
If you have any questions or desire further information with respect to this study, you may contact Ms. Jennifer Bell at [phone].

Contact for concerns about the rights of research subjects:
If you have any concerns about your treatment or rights as a research subject, you may contact the Research Subject Information Line in the UBC Office of Research Services at 604-822-8598 or if long distance e-mail to RSIL@ors.ubc.ca.

Consent:
Your participation in this study is entirely voluntary and you may refuse to participate or withdraw from the study at any time without any impact on your health care. You will be given a copy of this consent form for your own records. Your signature indicates that you consent to participate in this study.

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I have read the above information and I have had a chance to ask any questions about the study and my involvement. I understand what I have to do and what will happen if I take part in the study. I freely choose to take part in this study and I have a copy of the consent form.

__________________________                               __________________________
Please Print Name                                                Signature of Participant

__________________________                               __________________________
Signature of Witness                                                Date

Would you like to receive a copy of the final report from the study?
_____ (check mark) yes  _____ (check mark) no
Consent Form (Support Persons)

Title of Study: Improving patient autonomy in cancer clinical trials (IMPACCT)

Principal Investigator:
Lynda Balneaves, PhD, RN, Associate Professor, School of Nursing, UBC  604-822-7679

Co-Investigators:
Jennifer Bell, MA, PhD Candidate, Centre for Applied Ethics, UBC  647-462-2797
Anita Ho, PhD, Assistant Professor, Centre for Applied Ethics, UBC  604-822-4049
Harriet Richardson, PhD, National Cancer Institute of Canada – Clinical Trials Group and Assistant Professor, Queens University  613-533-6430
Kim Chi, MD, Clinician Scientist, BC Cancer Agency  604-877-6000 (672746)
Karen Gelmon, MD, Senior Scientist, BC Cancer Agency  604-877-6098 (2045)

Purpose:
The primary purpose of this study is to develop decisional support strategies for patients having to make difficult decisions about taking part in clinical trials. The overall aims include: 1) understand how cancer patients’ make decisions about clinical trial participation; 2) explore the personal, social, and health care factors that influence what is important to cancer patients in making decisions about clinical trial participation; and 3) identify how health care professionals can best support cancer patients’ decision making about clinical trials. In this study, we will be talking to patients and support persons (i.e., family members) as well as health care professionals.

Study Procedures:
In this study, you will be asked to participate in a 60 minute interview that will explore how you have been involved in a cancer patient’s decision about clinical trial participation (i.e., studies examining the effects of a treatment). You will be asked about your role in the patient’s decision-making process and how you supported the patient in making a decision. You will also be asked about what you see to be the challenges in making decisions about clinical trials and how cancer patients and support persons could be better supported in this process by health professionals. The interview will be digitally recorded and then transcribed. You will be paid a $25 honorarium for your time.

Project Outcomes:
Although the project outcomes will be determined by the research findings, possible research products will include: journal articles and reports for health research and clinical trial staff members, as well as for the general public. The information we get from this study might be used again for more research on clinical trial participation, but only if approved by the appropriate university committees.
**Risks and Potential Benefits:**
There are no explicit benefits or direct risks to you by taking part in this study. However, the interview will provide you with the opportunity to voice your opinion on your experiences. If the interview raises issues or feelings that you would like support in dealing with, the researcher can refer you to a counselor, or to other resources in the community. You can terminate your participation at any time, and you do not have to answer any questions that make you feel uncomfortable.

**Confidentiality:**
We will keep your name and information you provide strictly confidential. We will not use your name in the research reports and we use pseudonyms and codes instead of your name or other personal information in our notes and typed copies of the interview transcripts. Any documents and/or computer files linking your name to the pseudonym or codes will be kept separate from the data. All hard copies of documents will be identified only by code number and kept in a locked filing cabinet at the University of British Columbia. Electronic records will be kept on the local hard drives of team members’ office computers – all of which are password protected. The information collected in this study may be used for teaching purposes without revealing any information that would identify you.

**Contact for information about the study:**
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**Contact for concerns about the rights of research subjects:**
If you have any concerns about your treatment or rights as a research subject, you may contact the Research Subject Information Line in the UBC Office of Research Services at 604-822-8598 or if long distance e-mail to RSIL@ors.ubc.ca.

**Consent:**
Your participation in this study is entirely voluntary and you may refuse to participate or withdraw from the study at any time without any impact on your health care. You will be given a copy of this consent form for your own records. Your signature indicates that you consent to participate in this study.

*I have read the above information and I have had a chance to ask any questions about the study and my involvement. I understand what I have to do and what will happen if I take part in the study. I freely choose to take part in this study and I have a copy of the consent form.*

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Would you like to receive a copy of the final report from the study?

____ (check mark) yes

____ (check mark) no
Consent Form (Clinical Trial Personnel)

Title of Study: Improving patient autonomy in cancer clinical trials (IMPACCT)

Principal Investigator:
Lynda Balneaves, PhD, RN, Associate Professor, School of Nursing, UBC 604-822-7679

Co-Investigators:
Jennifer Bell, MA, PhD Candidate, Centre for Applied Ethics, UBC 604-707-5960
Anita Ho, PhD, Assistant Professor, Centre for Applied Ethics, UBC 604-822-4049
Harriet Richardson, PhD, National Cancer Institute of Canada – Clinical Trials Group and Assistant Professor, Queens University 613-533-6430
Kim Chi, MD, Clinician Scientist, BC Cancer Agency 604-877-6000 (672746)
Karen Gelmon, MD, Senior Scientist, BC Cancer Agency 604-877-6098 (2045)

Purpose:
The primary purpose of this study is to develop decisional support strategies for patients having to make difficult decisions about taking part in clinical trials. The overall aims include: 1) understand how cancer patients’ make decisions about clinical trial participation; 2) explore the personal, social, and health care factors that influence what is important to cancer patients in making decisions about clinical trial participation; and 3) identify how health care professionals can best support cancer patients’ decision making about clinical trials. In this study, we will be talking to patients and support persons (i.e., family members) as well as health care professionals.

Study Procedures:
In this study, you will be asked to participate in a 30 minute interview that will explore the organizational context of cancer patients’ decision making related to clinical trials. You will be asked about your role in the patient’s decision-making process and how you supported the patient in making a decision. You will also be asked about what you see to be the challenges in making decisions about clinical trials and how cancer patients and support persons could be better supported in this process by health professionals. The interview will be digitally recorded and then transcribed. You may be contacted after the interview and invited to take part in a 60 minute focus group with other clinical trial personnel to discuss the draft study findings and to provide input. You are not required to take part in the focus group if you so choose.

Project Outcomes:
Although the project outcomes will be determined by the research findings, possible research products will include: journal articles and reports for health research and clinical trial staff members, as well as for the general public. The information we get from this study might be used again for more research on clinical trial participation, but only if approved by the appropriate university committees.
**Risks and Potential Benefits:**
There are no explicit benefits or direct risks to you by taking part in this study. However, the interview or focus group will provide you with the opportunity to voice your opinion on your experiences. You can terminate your participation at any time, and you do not have to answer any questions that make you feel uncomfortable.

**Confidentiality:**
We will keep your name and information you provide strictly confidential. We will not use your name in the research reports and we use pseudonyms and codes instead of your name or other personal information in our notes and typed copies of the interview transcripts. Any documents and/or computer files linking your name to the pseudonym or codes will be kept separate from the data. All hard copies of documents will be identified only by code number and kept in a locked filing cabinet at the University of British Columbia. Electronic records will be kept on the local hard drives of team members’ office computers – all of which are password protected. The information collected in this study may be used for teaching purposes without revealing any information that would identify you.

**Contact for information about the study:**
If you have any questions or desire further information with respect to this study, you may contact Ms. Jennifer Bell at [phone].

**Contact for concerns about the rights of research subjects:**
If you have any concerns about your treatment or rights as a research subject, you may contact the Research Subject Information Line in the UBC Office of Research Services at 604-822-8598 or if long distance e-mail to RSIL@ors.ubc.ca.

**Consent:**
Your participation in this study is entirely voluntary and you may refuse to participate or withdraw from the study at any time without any impact on your health care. You will be given a copy of this consent form for your own records. Your signature indicates that you consent to participate in this study.

---

_I have read the above information and I have had a chance to ask any questions about the study and my involvement. I understand what I have to do and what will happen if I take part in the study. I freely choose to take part in this study and I have a copy of the consent form._

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Would you like to receive a copy of the final report from the study?

_____ (check mark) yes  _____ (check mark) no
Appendix VI: Demographic Information (Patients)

1) When were you born? ______/______/______
dd   mm   yyyy

2) What is your gender?
   □ Male
   □ Female

3) What is your marital status?
   □ Single
   □ Married
   □ Common-law
   □ Divorced
   □ Widowed

4) What is the highest level of education you have achieved?
   □ Some high school
   □ High school diploma
   □ Some college/trade school
   □ College/trade school diploma
   □ Some university
   □ Bachelor’s degree
   □ Graduate degree (Master’s, PhD)

5) What ethnic/cultural group do you most identify with?
   ______________________________________

6) When were you diagnosed with cancer?
   ______/______/______
   dd   mm   yyyy

7) What type of cancer were you diagnosed with?
   □ Breast
   □ Prostate
   □ Other (please specify):
   ______________________________________
8) Please check off all medical cancer treatment(s) you have received/are receiving for cancer:

☐ Surgery
☐ Chemotherapy
☐ Radiation
☐ Anti-hormone therapy
☐ Genetic counseling
☐ Other (please specify):

________________________________________
Appendix VII: Interview Guides

Interview Guide (Patients)

The purpose of this interview is to explore what it has been like for you to make a decision about whether or not to participate in a clinical trial. This interview will help inform the development of a decision support intervention for cancer patients faced with clinical trial decisions. Currently, we are struggling to get at the nuances of how patients make decisions about clinical trials. For this reason, you might find some of the interview questions repetitive; however, we often find that asking questions in different ways elicit slightly different and informative responses.

All the information we collect in the interview will be kept confidential and any identifying information will be removed. The interview will take approximately 60 minutes and will be digitally recorded. Do you have any questions before we begin?

1. Can you give me a quick background of your cancer experience to date, including when you were diagnosed and what treatments you have received and are currently receiving?

2. Are you currently enrolled in a clinical trial? If yes, for how long have you participated in the trial? Have you had previous experience with clinical trials? If so, can you please tell me a bit about those trials?

3. Overall, what is your opinion about clinical trials?
   Probes: What do you see to be their role in cancer care?
   What are your thoughts about patients taking part in clinical trials?
   What reservations, if any, do you have about clinical trials?

4. Currently, only about 5% of all Canadians diagnosed with cancer take part in clinical trials. Why do you think so few people are enrolled in clinical trials? What might be some of the barriers to people living with cancer taking part in clinical trials?

Now, let’s move onto your experience:

5. Can you tell me a little bit about how you first became aware of the clinical trial you are currently part of/ were invited to be part of?
   Probes: Who approached you?
   How was the trial presented to you?
   What sorts of information was shared?
   Who else was present during the conversation about the trial?

6. When you were presented with the clinical trial, were there also other treatment options that you and your health care team were considering at the time?

7. What did you do with the information about the clinical trial after it was presented to you?
   Probes: Did you have any immediate questions?
   Did you take the information home to review? Why/why not?

8. How long did you take to make a decision? Can you describe your decision making process?
Probes: What sorts of things did you consider? Did you seek any additional information? What were the motivating reasons to accept/decline/withdraw? Can you identify any beliefs and values that influenced your decision making?

9. When you were thinking about whether or not to take part in the clinical trial, what **information** was especially important to you in making this decision?
   Probes: Information about the impact of trial participation on your cancer? Information about side effects or time required of you to meet trial requirements? Information about the impact of trial participation on your overall health? Information about the impact of trial participation on your relationships? Information about the impact of trial participation on your work?

10. Can you tell me about any conversations you had with family, friends, or other healthcare professionals about being in a clinical trial?
    Probes: Did you speak to your spouse? Can you tell me about your conversation with your doctor? (*omit if cover in #5) What opinions were expressed about being a part of the trial? In particular, what was your perception of your doctor’s opinion about being a part of the trial?

11. People have shared with us that in making treatment decisions, they often consider where they are at in their lives. To what extent did your relationships (with your family, friends, or healthcare professionals) play a role in your decision making? Your work life? Your role in family or community activities?

12. To what extent was your decision making about being part of a clinical trial informed by your previous health care or treatment decision making experiences? Previous clinical trial experience?

13. How would you characterize your decision making about clinical trial participation? Was reaching the decision easy or difficult?
    Probes: What was easy/difficult about making the decision?

14. How informed do you feel you were in making this decision?
    Probes: What other information would have been helpful?

15. How involved were you in the decision to take part in the trial?
    Probes: Who made the final decision? How comfortable were you with your involvement in the decision? What would you do differently in the future?

16. What were the challenges, if any, you faced in your decision making? What helped you in making your decision?
17. How do you feel the process of being asked to participate in a clinical trial helped or hindered you in making a decision?

18. How similar or dissimilar is your treatment decision making to your clinical trial decision making?

19. How could the clinical trial recruitment process be improved?

Thank you for participating in this study. Is there anything else that you would like to share about your experience in making decisions about clinical trial participation?
Interview Guide (Support Persons)

The purpose of this interview is to explore how you were involved in a cancer patient’s decision-making process.

All the information we collect in the interview will be kept confidential and any identifying information will be removed. The interview will take approximately 60 minutes and will be digitally recorded. Do you have any questions before we begin?

1. How were you involved in the patient’s decision-making process to accept/decline/withdraw participation in the clinical trial?

2. What information was helpful to you in assisting the patient in making a decision?

3. What was your role in the patient’s decision making?
   Who made the final decision?
   How comfortable were you with your involvement in the decision?

4. What things did you do to support the patient in his/her decision making?

5. From your perspective, what were the reasons why the patient accepted/declined/withdrew?

6. What do you think was difficult for the patient in making the decision?

7. In your opinion, what gets in the way of patients making this decision? What helps patients in making this decision?

8. Did you feel the patient was under any pressure (e.g. social, familial) during the decision making process? If so, can you explain this a bit more?

9. How do you feel the clinical trial recruitment process supports or hinders patients in making a decision?

10. How could the clinical trial recruitment process be improved?

Thank you for participating in this study. Is there anything else that you would like to share about cancer patients making decisions about clinical trials?
Interview Guide (Clinical Trial Personnel)

The purpose of this interview is to explore the organizational context of personal decision making related to clinical trials.

All the information we collect in the interview will be kept confidential and any identifying information will be removed. The interview will take approximately 30 minutes and will be digitally recorded. Do you have any questions before we begin?

1) Why do you think patients accept/decline/withdraw from cancer clinical trials?

2) What do you think is most difficult/easy about this decision for patients?

3) How are you involved in patients’ decision-making processes?

4) What do you find, as a clinical trial personnel/researcher, to be most difficult about the clinical trial decision-making process?
   Probe: Recruitment process?
   Informed consent?
   Establishing competency?
   Others?

5) Respecting patient autonomy is an important part of clinical trial recruitment and the consent process. What does autonomy mean to you within the context of clinical trial recruitment?

6) In recent years, relational autonomy has become a subject of discussion within bioethics. What does relational autonomy mean to you within the context of clinical trial recruitment?
   a. What are some of the barriers experienced by patients from taking part in clinical trials? Personal issues? Social issues? Other issues?
   b. What are some of the factors that motivate patients to take part in clinical trials? Social? Personal? Other?

7) How do you feel the clinical trial recruitment process supports or hinders cancer patients in making a decision?

8) What do you see as being are the best practices for supporting patients’ decision making about clinical trial participation?

Thank you for participating in this study. Is there anything else that you would like to share about cancer patients making decisions about clinical trial participation?